RESEARCH REPORT

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Evaluating The Role Of Community-Based Models In Trial Design

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SEPTEMBER 2025

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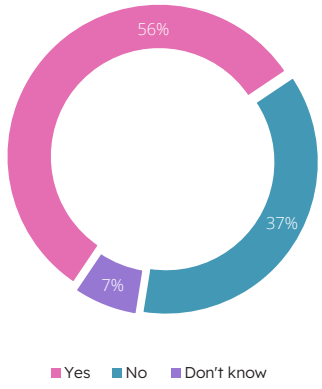
Evaluating The Role Of Community-Based Models In Trial Design

Community-based clinical trials may be gaining traction, but the industry's pace of adoption tells a more complex story. While community-based strategies, like mobile visits and mobile research sites, promise to improve recruitment, retention, and overall accessibility, implementation remains inconsistent across the industry. According to Citeline and EmVenio Clinical Research's *Trends in Clinical Trials Survey, 2025*, just 56% of organizations currently use community-based models as part of their trial strategy despite growing pressure to improve patient-centricity and diversity.

Figure 1. Utilize Mobile/Home Visits



Question: Does your organization currently utilize mobile/home visits as part in your trials?
Base: All responses (n=130).

To better understand how these models are being used and perceived today, Citeline and EmVenio Clinical Research surveyed 130 senior clinical operations professionals across the pharmaceutical, biotechnology, and contract research organization (CRO) sectors. Their responses offer a grounded perspective on where community-based approaches are delivering value, what's preventing scale, and how organizations are thinking about future integration.

This report draws on those findings alongside regulatory updates and broader market dynamics, to explore why enthusiasm for community-based trials has yet to translate into widespread, scalable execution.

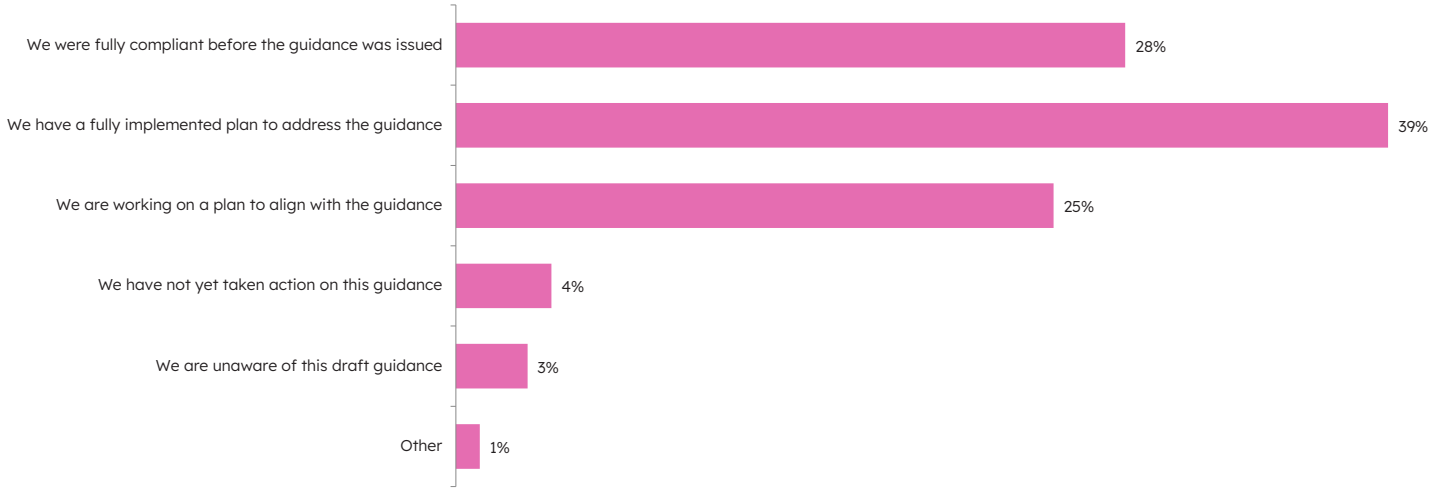
A Shifting Regulatory Landscape

Operational barriers continue to temper the uptake of community-based research models, but shifting regulatory expectations are adding a new layer of urgency – and in some cases, uncertainty.

Under the Food and Drug Omnibus Reform Act (FDORA), the FDA was required to finalize its Diversity Action Plan (DAP) guidance by June 26, 2025, mandating sponsors of Phase III and pivotal studies to submit demographic enrollment goals. Although the draft guidance was removed from the agency's website in early 2025 following a federal executive order, the statutory deadline remains in place, and legal experts suggest the requirement is still in effect, just temporarily obscured by political ambiguity.

Uncertainty aside, the regulatory expectation is clear: sponsors are now expected to consider broad patient representation as a scientific and strategic imperative, not a downstream compliance task. According to our survey, 67% of respondents stated that their organizations have a fully implemented plan or already had one in place to address diversity guidance. Notably, only a small minority reported taking no action to date, suggesting that regulatory influence is already shaping trial design decisions even in the absence of finalized guidance.

Figure 2. Regulatory Diversity Compliance



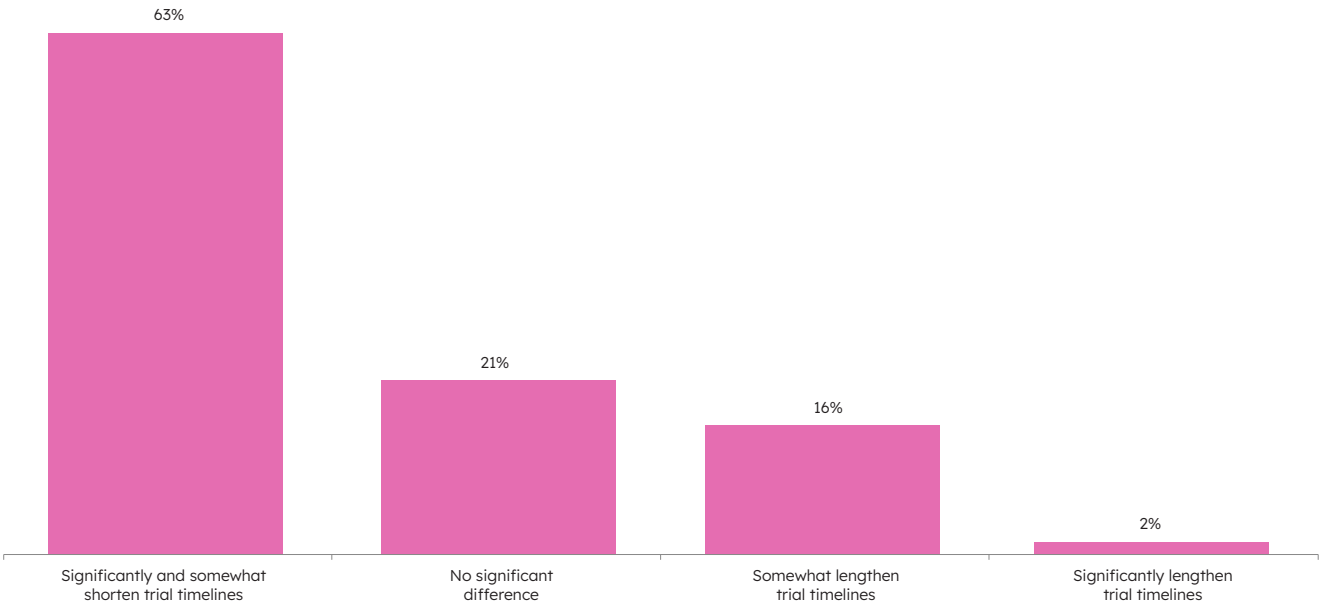
Question: How has your organization responded to the regulatory guidance on diversity for clinical trials?
Base: All respondents (n=130).

In parallel, implementation of the International Council for Harmonisation's (ICH) E6(R3) Guideline for Good Clinical Practice (GCP) is underway and set to take effect globally in mid-2025. The revision reinforces a risk-based approach to monitoring and data integrity while explicitly encouraging the use of flexible, fit-for-purpose technologies.

These principles align closely with community-based research methods, particularly those involving home or mobile visits and remote monitoring. However, they also raise the bar for execution: to remain compliant, sponsors must ensure robust systems for training, data capture, and quality control across increasingly distributed trial environments.

Against this backdrop, the survey findings reveal a clear tension between strategic intent and operational reality; nearly three-quarters of respondents (63%) believe these models can shorten clinical timelines.

Figure 3. Community-based Research Models Timelines



Question: How do community-based research models impact trial timelines compared to traditional site-based models?
Base: All respondents (n=129).

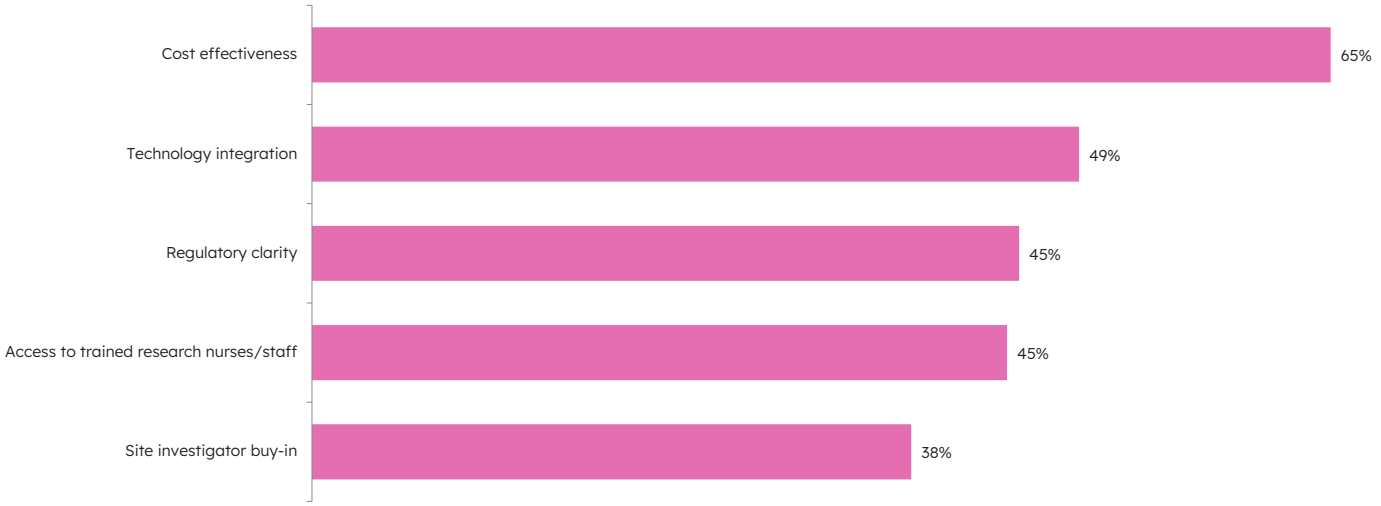
Yet despite this revelation, only 25% of organizations that have not fully implemented community-based research models are currently piloting these approaches, suggesting that enthusiasm remains tempered by logistical and structural challenges.

Regulatory pressure is emerging not only as a driver of innovation, but also as a potential source of complexity. While community-based models align with inclusion mandates and the principles of GCP modernization, they also expose persistent gaps in operational readiness.

This gap between intent and execution is born out in the data.

When asked which factors most influence the decision to implement community-based research, 45% of those surveyed pointed to regulatory clarity, making it one of the top three cited factors after cost-effectiveness and technology integration.

Figure 4. Community-based Research Implementation Decision



Question: Which factors most influence your organization's decision to implement community-based research in clinical trials? (Please select all that apply)
Base: All respondents; multiple answers permitted (n=130).

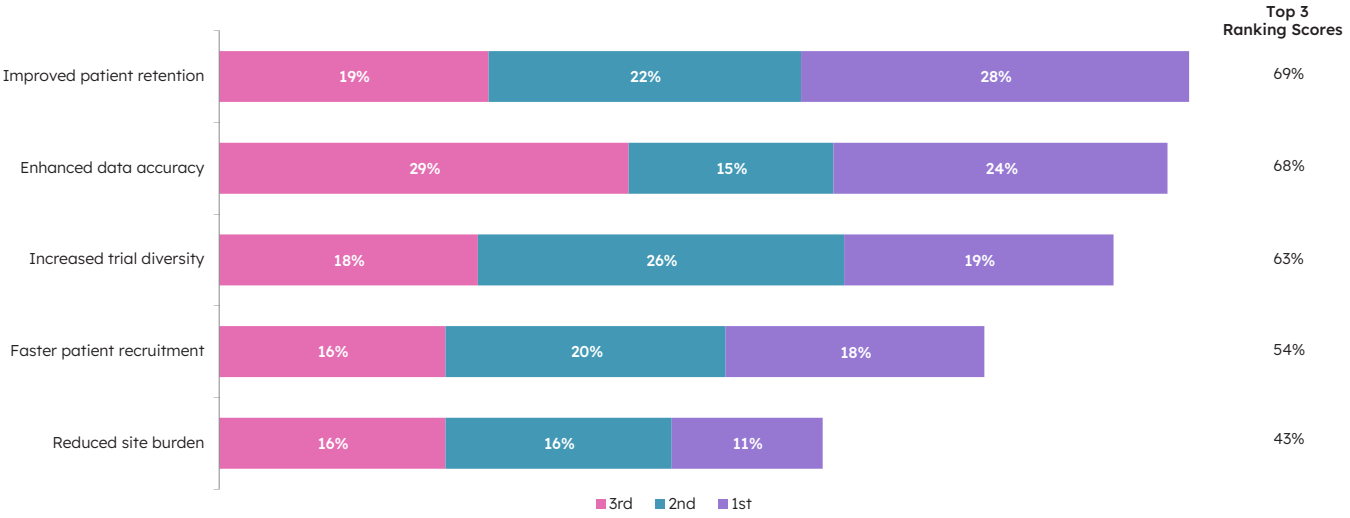
Among non-users of community-based models, 28% identified regulatory uncertainty as a core barrier to implementation, alongside concerns related to complexity, site staff support, and cost. These responses reflect a broader concern that without detailed guidance and practical case studies, many organizations remain hesitant to move beyond pilots or isolated use cases.

Perceived Benefits – And Why They Matter

Community-based models are not being adopted for novelty's sake – they're increasingly viewed as strategic tools for improving trial performance.

Almost three-quarters of respondents cited improved patient retention as a top benefit of community-based research, aligning with growing pressures to reduce dropout rates and strengthen data integrity, especially in long-term trials and among underserved populations.

Figure 5. Community-based Clinical Research Benefits



Question: Please select and rank the top 3 biggest perceived benefits of community-based clinical research in clinical trials?
(Please select 3 perceived benefits and assign a value/rank between 1 (most beneficial) and 3 (least beneficial) to each item. Value/ranks may not be repeated)

Enhanced data accuracy followed closely, challenging the assumption that community-based models compromise rigor. And, with faster recruitment coming in at third, it's clear these methods are also being recognized for their ability to expand access and ease logistical bottlenecks. In contrast, reduced site burden was identified as the lowest-ranked benefit, suggesting that perceived value is more affected by participant-facing outcomes than by internal operational efficiencies.

These findings counter the lingering notion that community-based approaches trade oversight for convenience. Instead, they reflect a broader industry shift toward inclusive, data-rich trial designs that prioritize both patient experience and scientific integrity.

This perspective is increasingly visible in cross-industry commentary, such as Scrip Asks... What Does 2025 Hold For Biopharma? Part 5, where senior leaders pointed to community-based clinics, remote monitoring, and hybrid site models as essential to expanding access and accelerating timelines, further solidifying the findings seen in Figure 3.

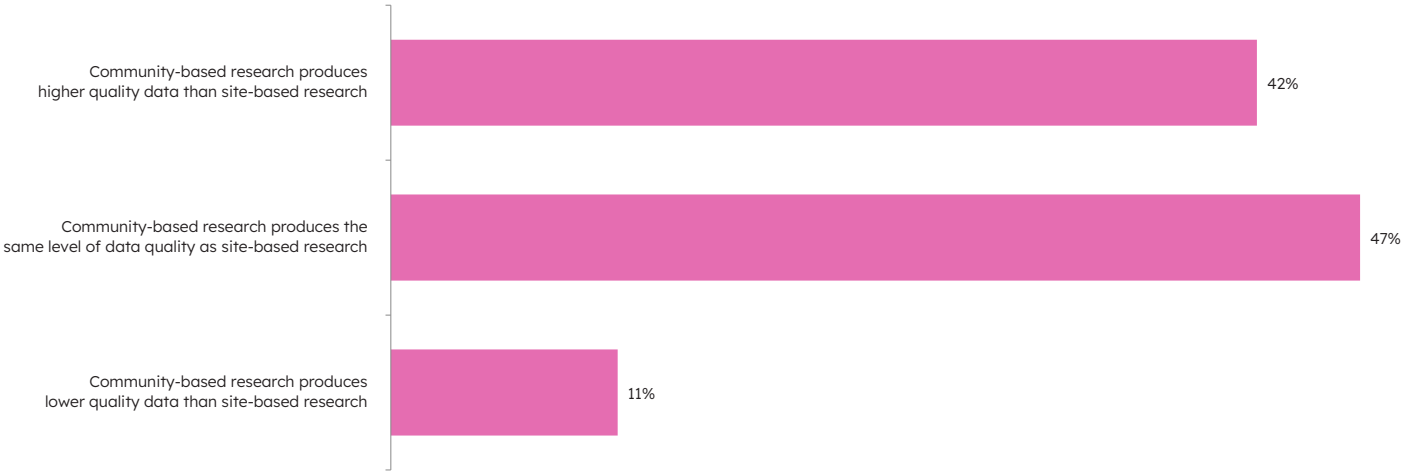
As trial designs grow more complex and patient engagement rises on the strategic agenda, removing barriers to participation is no longer optional – it's fundamental to trial success.

Reframing Perceptions Of Data Quality

Concerns over data integrity have long shaped industry attitudes toward community-based research. In traditional models, data oversight is tethered to physical site infrastructure, leaving some stakeholders wary of shifting trial activities into more distributed environments. But perceptions are evolving.

Approximately nine out of ten respondents believe community-based trials yield data quality that is either equivalent to or higher than that of traditional site-based models.

Figure 6. Community-based Research Data Quality



Question: In your experience, how does data quality from community-based research compare to site-based research?
Base: All respondents (n=127).

Nearly half stated they believe data quality is improved under community-based designs, while just 11% perceived it to be lower. This marks a notable shift in sentiment and challenges the assumption that home or mobile methods necessarily compromise control.

Ensuring data integrity in a community-based model isn't without its challenges. Distributed trial settings introduce a new layer of complexity, from staff training and oversight to technology integration and GCP compliance. Yet the perception that these approaches

compromise quality is beginning to shift. Survey data shows growing confidence in the scientific rigor of home and mobile-based designs, especially when supported by purpose-built infrastructure.

This reframing isn't happening in a vacuum. The broader industry conversation in 2025 is steadily moving toward decentralization by design, with trials that are inclusive, adaptive, and risk-aware by default. Regulators are reinforcing this shift.

ICH E6(R3) not only allows for remote methods; it encourages them, provided the process, documentation, and oversight are appropriately structured. In this context, proximity to a site matters less than the reliability of the systems underpinning the data.

What's emerging is a more mature view of what compliance and quality mean in a post-pandemic trial landscape. Not less control—just different control.

Confidence in community-based models still varies, particularly among organizations that have yet to pilot or operationalize them. Among non-users, 24% believe these approaches result in lower data quality. Without firsthand experience, perceptions tend to be shaped more by assumption than evidence.

To shift that perception, the focus must now turn to demonstrating consistent success. Strong case studies, audit-ready protocols, and transparent supplier performance will all be essential. Moving community-based research from experimental to expected will require more than theoretical alignment. It will take proof that these models can deliver – not just in principle, but in practice.

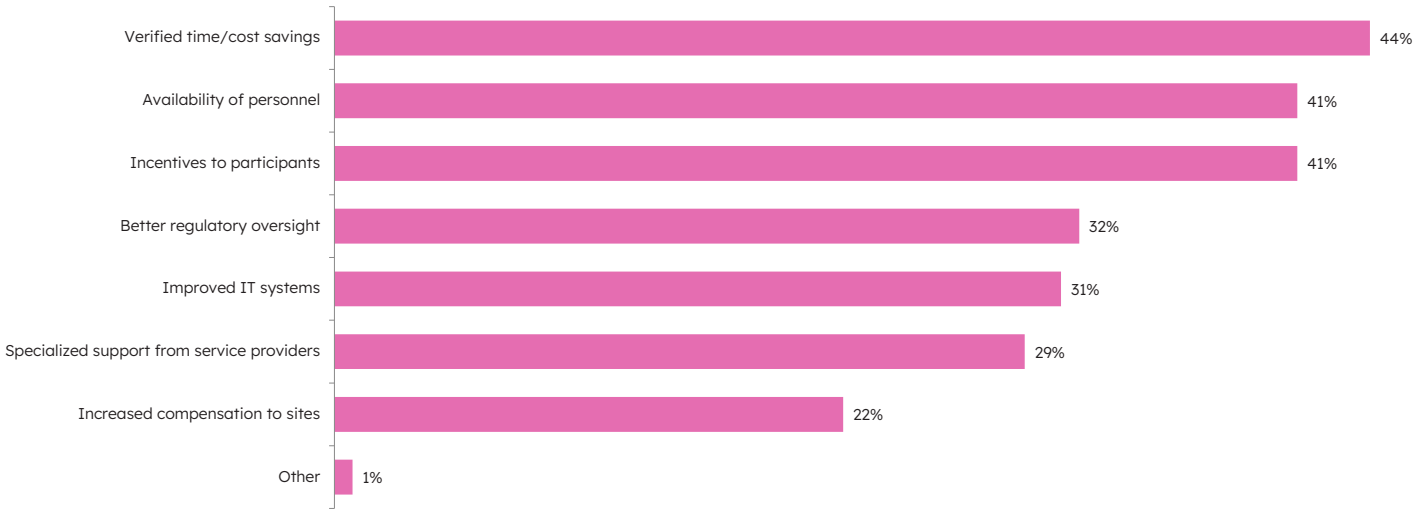
What Would Encourage Broader Adoption?

Community-based models continue to generate interest, but interest alone doesn't guarantee movement. Adoption depends on a different equation: credible return on investment (ROI), operational backing, and visible proof points.

When asked what would most encourage broader use of community-based research, 44% of respondents pointed to verified time and cost savings. It's a telling signal. The narrative around patient-centricity is no longer enough on its own; stakeholders want evidence that these models can deliver efficiencies across recruitment, data collection, and site engagement. That pressure reflects broader market dynamics as biopharma companies navigate tighter pipelines, rising development costs, and investor scrutiny around speed to market.

Other incentives aren't far behind. Participant compensation and access to trained personnel were each selected by over one-third of respondents. The first speaks to a fundamental reality: even the most thoughtfully designed study will fall short if patients aren't supported to take part. The second highlights structural constraints. Without the right workforce and systems to manage their deployment, scaling community-based visits becomes more ambition than outcome.

Figure 7. Community-based Model: Migration Factors



Question: What factors would most encourage you to move more clinical trials or parts of them to a community-based model? (Please choose up to three factors)
Base: All respondents; three answers permitted (n=130).

A further 32% of respondents cited better regulatory oversight as a key enabler – and it's not hard to see why. Compliance anxiety continues to shadow adoption efforts, especially as sponsors await clarity on the FDA's DAP requirements and prepare for the global rollout of ICH E6(R3). In this context, organizations may hesitate to expand into community-based models without a clearer view of inspection readiness and audit expectations.

These findings reflect a broader shift in mindset. In 2025, innovation must prove itself operationally. Cost-effectiveness, risk mitigation, and delivery consistency now define whether new approaches move beyond pilots.

This perspective is becoming increasingly mainstream. R&D leaders across the industry have pointed to the importance of infrastructure, from satellite sites to localized delivery hubs, as the foundation for equitable trial access. There's a growing consensus that access and diversity are strategic priorities, but executable, audit-ready processes must match them.

Commercial logic reinforces this urgency. Delays in enrollment and high dropout rates cost time, capital, and pipeline momentum. If community-based models can deliver even marginal gains across those metrics, they present a clear business case. But until those gains are demonstrated more widely – with data, not anecdotes – many organizations will stay in test-and-learn mode.

Moving the model forward requires more than strategic alignment. It demands cross-functional ownership, real-world validation, and a willingness to invest beyond individual protocols. Because in today's landscape, testing a new idea isn't the hard part – it's proving it can scale.

Turning Pilots Into Practice

Momentum is building, but the industry hasn't crossed the threshold from pilot to paradigm shift. That could soon change.

According to the survey, 72% of respondents expect the role of community-based research to increase over the next five years. This expectation isn't just about improving the participant experience but also reflects deeper shifts in how organizations define success in trial delivery. Cost containment, faster timelines, and population-level representativeness are becoming non-negotiable. Community-based research, when executed well, supports each of these goals.

Yet recognizing potential is not the same as being operationally ready. When asked to rank their top challenges to implementing community-based models, non-users most frequently cited cost as the primary barrier, followed by complexity and lack of site staff support.

Regulatory uncertainty, while selected less often as the top challenge, still appeared as a contributing concern for many respondents. These rankings suggest that while compliance considerations remain on the radar, the most immediate roadblocks to adoption are logistical and resource-based.

The shift from concept to standard practice will likely hinge on a few pivotal enablers.

First, a broader availability of trained personnel is essential.
Community-based models are only as strong as the mobile clinicians and operational teams delivering them, many of whom operate beyond the walls of traditional sites. Without reliable access to experienced partners, even well-intentioned designs falter.

Second, investment in infrastructure must continue.
This investment includes not only digital tools and remote monitoring platforms but also the operational backbone required to support community-based research more broadly. Standardized procedures for protocol adherence, data verification, and regulatory documentation must extend across distributed settings – including mobile visits, community-based sites, and hybrid trial approaches. As the ICH E6(R3) revision raises the bar for quality and consistency, strengthening these foundational elements is more critical than ever.

Finally, real-world data will be a differentiator.
Stakeholders want proof that community-based models shorten timelines, improve patient engagement, and uphold protocol compliance. More case studies that are rigorously tracked, independently validated, and regulator-approved will help shift perception from risk to return.

There are signs that this shift is already underway. Industry leaders are increasingly framing trial design decisions through the lens of equity, efficiency, and strategic collaboration. Community-based methods are being treated less as experiments and more as essential tools for delivering trials that reflect the complexity of real-world care.

Whether that translates into universal uptake remains to be seen. But the direction of travel is clear: the future of trial execution lies in flexibility, proximity, and proof.

Redefining Success In A Community-Based Future

If community-based models are to sustain momentum beyond their current phase of experimentation and pilot testing, the industry needs to do more than overcome operational friction. It needs to rethink the definition of trial success itself.

Traditional metrics of performance, such as enrollment speed, protocol adherence, and site productivity, remain vital, but they don't fully capture the real-world dynamics that are increasingly shaping trial design. In a global context marked by widening disparities in healthcare access, demographic shifts in disease burden, and growing regulatory scrutiny around inclusion, success can no longer be defined solely by internal KPIs.

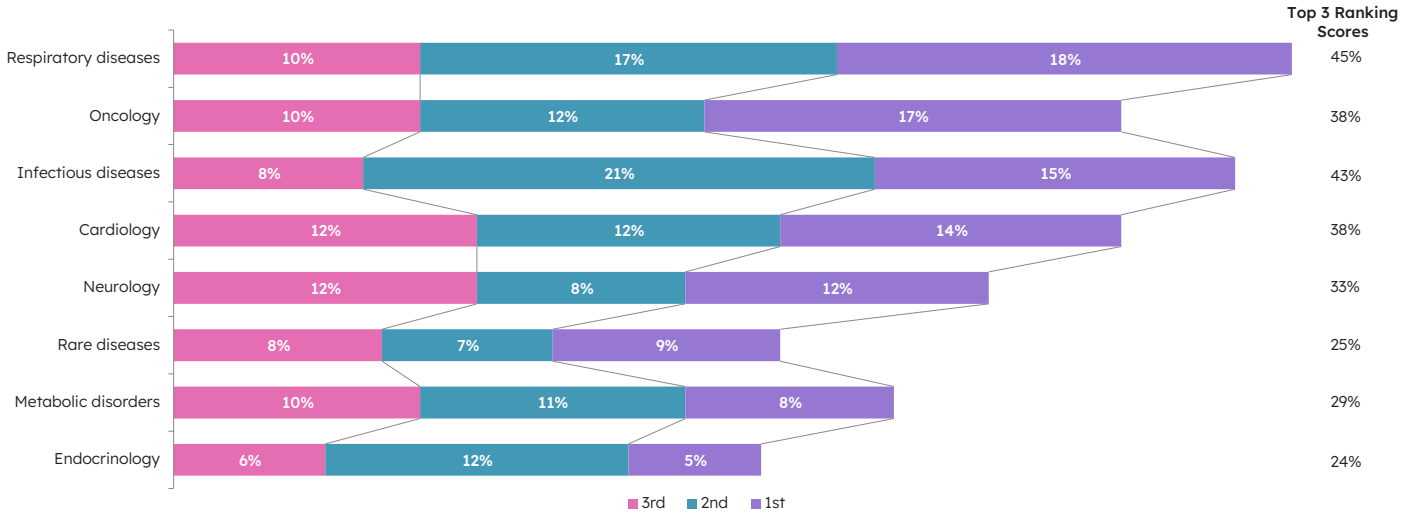
Instead, we're entering an era where trial design must deliver on multiple fronts at once. Community-based research models sit at the intersection of those priorities. They offer a pathway to reach populations historically excluded from research, generate more generalizable data, and reduce patient burden without compromising oversight or quality, provided they are implemented with the right infrastructure.

Importantly, community-based approaches also provide an avenue for differentiation. In competitive therapeutic areas, demonstrating not only innovation in molecule development but also innovation in trial design can shape how regulators, payers, and patients engage in research. In this way, the trial model becomes part of the product story.

Yet uptake still hinges on evidence, not enthusiasm. The industry needs clearer case studies, robust ROI modeling, and longitudinal data that link community-based delivery with downstream outcomes such as patient adherence, real-world effectiveness, and regulatory acceptance.

Moreover, sponsors must resist the urge to frame these models as 'alternative'. Community-based methods shouldn't be the exception – they should be one of many equally valid tools available to meet the needs of increasingly complex pipelines and globally dispersed patient populations. The mindset shift required here isn't trivial, but it is necessary.

Figure 8. Therapeutic Areas Best Suited To Community-based Research



Question: Please select and rank the three therapeutic areas you see the most potential for community-based research in clinical trials?
(Please select 3 therapeutic areas and assign a value/rank between 1 (most beneficial) and 3 (least beneficial) to each item. Value/ranks may not be repeated)
Base: All respondents; three answers permitted (n=130).

There are signs of change. Emerging partnerships between sponsors and service providers are beginning to institutionalize community-based infrastructure. Trial networks are expanding their geographic footprint. Technology vendors are offering integrated platforms that bridge data collection across traditional and non-traditional settings. These are the mechanisms of scale – and if sustained, they will form the architecture of the next generation of trials.

Ultimately, this shift will not be driven solely by regulations or technologies. It will be driven by organizations willing to lead and those willing to embed community-based trials into their current strategies.

Today's real competitive advantage isn't just speed. It's the ability to design trials that are inclusive by default, efficient in design, and credible at scale.

EmVenio Clinical Research, a Professional Case Management subsidiary, operates from U.S. and European headquarters with a team of approximately 5,000 professionals supporting clinical trials across more than 80 countries. Our community-based sites and mobile research services expand access for trial participants, while enabling sponsors and CROs to execute high-quality studies at speed and scale with clean, reliable data and consistent results. By bringing trials directly to patients in their homes, communities or places they gather, we enroll populations others miss, helping create a complete and more inclusive picture of human health. Our approach is grounded in empathy, expertise and close collaboration—bridging the gap between science and the people it serves because true progress only happens when research reflects the real world.

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