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Community-Based Infrastructure for Inclusive Research: Engaging the Private Sector

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Introduction

The COVID-19 pandemic revealed prominent gaps in our collective clinical trial infrastructure and stark differences in health outcomes across various populations. A community-based infrastructure that facilitates access to clinical research and health care has the potential to improve health outcomes for all, but questions remain about what such a system would look like on a national scale. They include considerations around finding participants in the places they live and receive care, and determining who would be responsible for creating and maintaining such a system.

> **"Of the more than 2,500 COVID-19 therapeutics trial arms launched with plans to enroll more than half a million participants, only 5 percent were randomized and adequately powered and therefore could be considered to have generated actionable evidence. This problem is not limited to COVID-19 therapeutic development; it exists across the biomedical innovation ecosystem. One reason for trials falling short of expectations is the ecosystem's inability to run trials close to communities in order to rapidly and efficiently engage large and diverse groups of patients in clinical research."**
>
> **Janet Woodcock**
> Principal Deputy Commissioner, US Food & Drug Administration

FasterCures aims to bring together commercially and federally sponsored community-based research networks to help build local capacity and involve more communities in clinical research, to use resources efficiently throughout the research enterprise, and to realize an "ecosystem of excellence" in a better-coordinated national system. In the first issue brief in this series, *Lessons from the Pandemic for Federal Action*, we focused on the federally funded trial infrastructure, as well as federal policy and resources that might be needed to begin to knit together an ecosystem of excellence out of islands of pilots. We highlighted a number of common infrastructure gaps that make it challenging to run more trials in more places to reach more participants. Recommendations for action included:

- better coordination of government-funded networks and sites;
- alignment of federal requirements for data collection and research conduct across agencies that fund research and care networks;
- identification and funding of research priorities that will address the needs of communities and serve to build and sustain research capacity;
- modernization of regulation and use of technology to engage more patients; and
- building trust through sustained consultation, support, and a commitment to communicating and implementing the results of research at the community level so that everyone may benefit.

A major step in achieving a coordinated system is to improve involvement of the private sector, which funds and executes the majority of clinical trials. To that end, in late 2022 FasterCures conducted a series of key stakeholder interviews and held a leadership roundtable to discuss and consolidate learnings from a variety of private-sector actors. Participating organizations represented the biopharmaceutical industry, contract research organizations, site-management and "last mile" organizations working to bridge gaps between community sites and those conducting research, health systems and community care providers, and technology and health data companies.

In this brief, we examine the private-sector clinical research landscape for a better understanding of the gaps sponsors and their partners are seeing and to identify opportunities for collective solutions.

Very few Americans participate in clinical research, as patients *or* as physicians.

- Only about 3 percent of physicians and patients participate in clinical trial research that leads to new therapies, according to the American Medical Association and Fierce Healthcare, citing Food and Drug Administration (FDA) data.
- According to the FDA, in 2020 75 percent of trial participants were White, 11 percent were Hispanic, 8 percent were Black, and 6 percent were Asian.

Most Americans live close to community hospitals or retail pharmacies, which could expand ease of access to clinical trials conducted from these nontraditional locations.

- Rural Americans live 10.5 miles, on average, from the nearest hospital, according to the Pew Research Center.
- Eighty-five percent of Americans live within 10 minutes of a CVS, 78 percent live within five miles of a Walgreens, and 90 percent live within 10 miles of a Walmart, according to company press releases and as cited in Clinical Leader.

Although much earlier work has focused primarily on academic medical centers and federally sponsored research networks and sites, the private sector is responsible for the majority of trials in the US.

- According to 2021–2022 data from clinicaltrials.gov, 8,247 clinical trials in Phases 1–4 were started in the US. Of that total, 13.3 percent were funded by the National Institutes of Health (NIH) and other federal agencies; 24.9 percent by "other," which includes organizations such as universities, cancer centers, and hospitals; and 61.7 percent by industry.

Building Research Capacity in People and Places

Many participants in clinical research recognize that expanding community-based infrastructure can have numerous benefits, including improved access to research, diversity of providers and participants, awareness of new treatments in a wider variety of practices, and perhaps trust in the biomedical research and innovation system. Yet difficulties persist in realizing this vision. Several key issues are affecting the private sector as it works to expand and sustain community-based sites and partnerships for clinical research. Some are similar to the challenges confronting federal agencies, as discussed in FasterCures' prior work—and many sites run trials for both public- and private-sector sponsors—but some are specific to the private sector or have changed with the evolving landscape of community engagement. The following section identifies structural barriers, key insights, and recommendations to spur action.

Key Issue: Capacity and Coordination

Structural Barriers

- Nontraditional research sites and partners often lack the financial and human capital or the technical tools required to engage regularly and productively in research opportunities.
- Multiple sponsors, both private and government-supported, approach and work with many of the same sites and partners but are not coordinated or synchronized in requirements or systems.

Key Insights

- Awareness of the capacities, capabilities, or even common practices between publicly and privately funded research networks seems limited at times, constraining opportunities for coordination in a national, system-wide effort.
- The same employees often perform similar work at multiple sites for different sponsors. This practice uses time resources inefficiently, overburdens individual staff members at sites, and works against building trust with the biomedical research enterprise.
- It is inefficient and overwhelming for individual sponsors or small groups of them to reach out ad hoc to small groups of partners such as Historically Black Colleges and Universities or Minority-Serving Institutions. A centralized platform or clearinghouse could help each of these groups interact more efficiently, share learnings more broadly, and direct resources to other areas of research rather than repeatedly building the same starting infrastructure.

Recommendations for Action

1. **Build and maintain an accessible, national clinical trial inventory system.** This system could be analogous to, and perhaps compatible with, NIH's **Clinical Trial Capacity Inventory** and index community and commercial sites' capabilities and interests to help distribute research more efficiently.
2. **Develop a public-private clinical trial infrastructure coordination hub.** This hub could streamline interactions among research sponsors and site networks and encourage competition on the quality of clinical studies and their outcomes, rather than on building proprietary or duplicative site networks. The hub could also provide technical assistance and support for establishing new clinical trial sites and training providers on the conduct of clinical trials.
3. **Establish a public-private clinical trial learning collaborative system (a "collaboratory").** This group could provide a forum to share best practices, broaden awareness of the research capacities of both sectors, and improve cross-sector coordination to lessen the burden on individual sites.

SOLUTIONS IN ACTION

ACT@POC™

The Coalition for Advancing Clinical Trials at the Point of Care (ACT@POC™) aims for better integration of clinical research and care. According to the Duke-Margolis Center for Healthcare Policy, the distinguishing characteristics of point-of-care trials are that they are conducted in routine care settings and embed enrollment, randomization, and data collection into electronic health records (EHRs) as much as possible. They tend to be suited to addressing priorities relevant to health-care systems, such as comparative-effectiveness studies, and feature simpler, more streamlined designs.

ACT@POC is facilitating point-of-care research by:

- considering what is needed to move from a model of fee-for-service health care to a model that directly incentivizes improving health outcomes;
- developing longer-term platform initiatives that address common chronic conditions and priorities directly relevant to health systems using already-approved drugs; and
- collaboratively prioritizing policies that need to be clearly addressed among federal agencies, researchers, and health systems to facilitate relevant, straightforward, point-of-care research.

Key Issue: Education and Outreach

"Mistrust in medical research does not stem from a single event, so we can't be naive enough to think that one action is going to make a difference in correcting it."

Jamie Langley
Global Head, Parexel® Academy

Structural Barriers

- Diversity and inclusion are not trial-specific, but clinical research can be quite transactional or episodic, which can lead to inadequate engagement and mistrust. Long-term commitment and relationship-building with community sites and partners are required but not always rewarded in commercial research.
- The value proposition and incentives for sites, investigators, and communities that have not historically been engaged in research may differ from those of traditional sites.

Key Insights

- For community sites to participate fully in clinical research, their needs must be taken into account in advance. For example, translations of research materials cannot become available only long after English-language versions; delay introduces a structural problem that directly contributes to lower participation in research by diverse populations.
- There is a need to build trust and relationships at many levels of the biomedical research system. Although building trust between study participants and researchers is most often discussed, there is a real benefit to building trust between sites—particularly new sites—and sponsors.

- Health-care systems are already overburdened; therefore, research participation must present a good value proposition for dedicating the necessary time and attention to support a research program. This value proposition can be monetary, but it may be equally compelling to demonstrate improved health outcomes and satisfaction among research participants.
- Communicating information back to community sites and health systems can validate the return on investment. It also enables better planning for staffing studies; more realistic estimates of staff time requirements; and better preparation to allocate additional resources for future studies, such as hiring dedicated research coordinators.

Recommendations for Action

4. **Develop metrics frameworks to assess the value of research opportunities for communities.** These metrics frameworks should address the evaluation of the relevance of studies to specific communities, as well as the outcomes and value to all stakeholders on the back end. Federal agencies should support the development of an evidence base showing linkages between access to clinical research, on the one hand, and improved health outcomes and community engagement on the other.
5. **Build bidirectional data sharing into contracting agreements to systematize learning.** Research sponsors should routinely communicate and share data on outcomes with newer community investigators and sites to improve performance over time and support their sustained and productive engagement in the clinical research system.
6. **Include community and site representatives in clinical trial infrastructure coordination hubs.** Their expertise should be sustainably incorporated to improve research and build trust collectively with communities.

SOLUTIONS IN ACTION

Walmart

The Walmart Healthcare Research Institute (WHRI) offers access to clinical trials as part of the care available to Walmart customers and aims to expand access to clinical research at WHRI locations or through referrals to larger centers as needed.

- The company has around 4,700 stores with pharmacies across the US, about 4,000 of which are in federally designated medically underserved areas. It has established 32 health clinics, all in medically underserved areas and tied to Walmart in-store pharmacies and optical centers.
- Key aims of the research program are to:
    - focus on conditions affecting the communities where its research centers are located and share referrals to studies directly and immediately relevant to patients' needs;
    - develop a digital patient platform to allow research participants direct access to their health data, assist with long-term care monitoring, and offer patients reminders and suggestions for regular care to discuss with health-care providers (HCPs); and
    - improve representation of diverse populations in trials and build trust in research through engagement with the communities the company serves.

Key Issue: Human Capital

Structural Barriers

- Like federal agencies, private-sector sponsors struggle with improving diversity among clinical trial staff at all levels, not just investigators; enhancing cultural competency across the board; and broadening mentorship opportunities for early-career staff.
- Personnel infrastructure and training must adapt to meet the needs of a broader, more inclusive clinical research system and to accommodate sites with fewer resources or less experience.

Key Insights

- To support community-based infrastructure, the research workforce must be broad. One person at each site, sometimes repeating the same tasks for different sponsors, does not have the capacity to address needs realistically at each site.
    - Traditional researchers and site staff should be part of a broader research workforce, as should nontraditional recruits such as community health workers, faith-based and other trusted community leaders, and health educators. This broad workforce offers significant value in supporting a network that is prepared for both predictable and unpredictable health research and has a stable reach and connection to many communities and locations.
- Education about clinical research, industry-sponsored trials, and diversity and inclusion needs to occur earlier in medical education and be a part of more programs to balance the workforce over time.
- Commercial research is subject to high turnover in on-site staff positions. There are limited career pipelines or practical training programs for early training or mid-career transitions to build a robust pool of clinical research coordinators or other site staff. Mentorship opportunities for investigators are similarly limited.
- Lack of diversity among investigators and site staff is a systemic problem that is difficult to address at the level of an individual research site. An interim step could be to focus on recruiting diverse patient navigators from local communities.
- Too often, the approach for starting research at a community site is to dedicate a small portion of an existing staff person's time to the new effort. Eventually, this may lead to difficulty for the site because of limited capacity to secure new studies or proactively engage with local communities around research availability.
- Reliance on overly complex trial designs and the inclusion of procedures that collect data unrelated to study endpoints are common, adding to burdens on participants and sites. These make it more difficult to achieve an accurate estimate of the time required to conduct a trial, with downstream implications for conventional fee-for-service billing models.

Recommendations for Action

7. **Create training programs for career pathways in clinical research at every level, not just investigators.** Specific programs should be developed to support the roles of patient navigators, including community health workers and promotores, to support clinical trial education and awareness campaigns with community partners.
8. **Modify contracting and payment models to encompass all the human capital involved.** Traditional and nontraditional workers need consistent funding to support community outreach efforts seamlessly and consistently. Funding for community outreach programs should be built into sponsor contracts and agreements.
9. **Involve representatives of nontraditional sites and community partners in research planning.** Include community and patient representatives in the up-front design of a clinical trial protocol to build trust and engagement in the research study.

10. **Emphasize research as an integral part of care.** Develop and distribute common training materials for clinicians that emphasize clinical research as an option that can—and should—be available to every person who enters a community provider site.

SOLUTIONS IN ACTION

Javara Research

As an integrated research organization (IRO), Javara aims to introduce efficiencies across the research process at scale. Embedding clinical research staff and infrastructure into community health-care organizations, Javara, in essence, delivers the services of a contract research organization (CRO). The approach tailors support to health systems rather than research sponsors.

- In the IRO model, Javara acts as a centralized organization to manage the conduct of clinical research, embedding staff and technology on-site. In exchange, hospitals must commit to offering clinical research as a care option to all the patients they serve.
- The value proposition for health systems is the opportunity to participate in the conduct of clinical trials, providing the high-quality care associated with research without significant additional burden on providers and supporting staff. Health-care systems participating in such partnerships report improved health outcomes, patient engagement in medical care, and provider experience.

Key Issue: Budgeting and Planning

Structural Barriers

- Standard contracting language and budgeting processes have not kept pace with societal and sponsor demands for increased inclusion, which has led to stress on sites.
- Community sites often do not have the resources to manage complex contracting processes with multiple sponsors and are often not reimbursed in a timely manner to manage their internal operations.

Key Insights

- Demand for including diverse populations in trials is increasing, but necessary updates are not always reflected in sponsor contracting and timelines. Inclusivity, community engagement, and flexible participation options (e.g., telemedicine or home health) are all important and increasingly expected from trial participants and sponsors alike but require dedicated staff and funding.
- These flexibilities must be built into project plans early in the research. It is inefficient to add them only when a trial is handed off to a CRO; the objectives are difficult or impossible to achieve as an afterthought.
- The updates would not necessarily require additional funding. Clarity would be helpful even on issues such as whether patient recruitment funding can support community engagement efforts or whether contracting and funding could be flexible to support differing patient needs in rural versus urban areas.

Recommendations for Action

11. **Revise standard contracting language for existing and new contracts to include community engagement activities in patient-recruitment line items.** Community engagement is a core part of patient recruitment and retention, and industry should advocate for policy changes if necessary.
12. **Adjust standard funding practices to match the variable needs of sites.** Sites differing by geography or experience levels may have different needs, and resources should be allocated accordingly.

Key Issue: Sustainability

Structural Barriers

- Infrastructure at community sites is costly and time-consuming to establish for the sites, staff, and sponsors alike. Maintaining this infrastructure and knowledge base requires a long-term investment as well as predictable incoming work. However, predicting upcoming needs or confirming investment is difficult when future research is uncertain.
- Returns on investment can be slow for organizations or companies accustomed to making quarterly decisions.

Recommendations for Action

> **"Regarding engaging newer or less-experienced community-based sites and investigators, it seems like there's a prevailing attitude of 'I want to do research with the community, I want to engage with a diverse patient population,' but in reality, it's very difficult to get these sites selected for a trial. We have to change that way of thinking—or address that hesitation—if we are going to have a deeper reach."**
>
> Kerry Gorman
> Senior Director, Strategic Site Solutions, IQVIA

- The number of community research sites virtually exploded during the pandemic. The greatest need now is for support to continue and maintain this new infrastructure to reach communities and forestall the tendency for individual study teams and sponsors to revert to established research sites.
- Sponsors have an opportunity to support capacity-building at smaller sites with limited experience; even if the volume of participatory trials is low, inclusion brings value to the sites and the patient communities.
- A growing marketplace of companies and organizations is working to connect community sites with clinical research. Solutions are needed to help the community sites efficiently and sustainably attract research.
    - There may not be enough research to sustain the infrastructure being built, and too many trials may compete for the same sites. The great need is for creative ideas around companies or HCPs referring to other groups or to existing trials with which they are not involved. Though complex, such an incentive structure is necessary if improved health outcomes are the goal.

Recommendations for Action

13. **Cultivate patience for long-term relationships and commitments within the realities of quarterly reporting.** Benchmarks for positive investment trends could be metrics that measure research inclusivity or diversity of trial participants over time.

14. **Redesign incentives for participating in a sustainable, coordinated research network that includes community sites.** Reimbursement policies could reward referrals to existing trials in a supported network rather than requiring community sites to perform research directly in order to participate.

SOLUTIONS IN ACTION

Inato

A model used by the global tech company Inato helps community research sites and hospitals with some experience in clinical trials gain visibility and access to upcoming studies, in turn providing pharmaceutical companies with access to diverse patient populations. The Inato platform matches these qualified but lesser-known community sites to the trials best suited to their teams and local populations, broadening site experience and helping sponsors connect sustainably with them. Over time, repeated positive interactions between community sites and sponsors can build trust across the industry.

- By collecting data about each site's capabilities, interests, diversity, experience, and attributes, the platform helps sites showcase their strengths to improve the likelihood of selection and streamlines their trial review process. It also supports research investment decisions and facilitates sustainability by increasing the transparency of trial details and timelines.
- With more data on these sites and their unique capabilities, pharmaceutical sponsors build trusted relationships with unfamiliar yet high-potential community sites. Sponsor relationships with these sites increase efficiency with faster activations and more precise ways to achieve diversity goals.

Key Issue: Technology and Data

Structural Barriers

- Lack of data standardization and harmonization contributes to the burden of variable requirements and platforms for data collection weighing not only on federal and private-sector research networks but also on community sites interested in trial participation.
- Community sites struggle with equitable access to technology regarding tools that enable remote access to trials and that facilitate complex medical procedures.

Key Insights

- The lack of standardization and harmonization is a burden on community research sites. Even the need for multiple log-ins and passwords on different data platforms can burden new investigators.
- The research enterprise generally does not collect enough data about personal characteristics that individuals care about and that could affect treatments and outcomes. Only 43 percent of clinical trials collect data on race and ethnicity, let alone gender identity, sexual orientation, socioeconomic status, and other personal characteristics.

Recommendations for Action

15. **Develop single sign-on software capabilities to relieve the burden of participation.** Federal regulators or industry standards bodies should explore simple, site- or investigator-focused technology solutions.
16. **Evaluate and address technology needs of community sites.** Share knowledge, equipment, and resources to support remote trial access or perform trial-related medical procedures when possible.
17. **Collect US Census race and ethnicity category data on every participant in every trial.** This would be a first step toward addressing the data gap. Sponsors should build such requirements into contracts with health systems. Ensure that community sites have the technological capabilities and supports necessary to collect this information.

SOLUTIONS IN ACTION

Oracle Cerner's Learning Health Network

Oracle Cerner has a well established reach into communities and a pre-existing infrastructure through its EHR platform that can be used for research. To capitalize on this possibility, Oracle Cerner launched its Learning Health Network in 2020.

- The Learning Health Network is an exchange by which participating health systems that opt in gain access to a broad database of deidentified data in exchange for contributing their own data. The network also connects research coordinators and institutions to participate in informal mentorship programs, helps match clinical trial opportunities to appropriate sites, and enables participating health systems to recruit patients for existing trials.
- As of October 2022, around 100 million patient records were included among more than 100 participating health systems, including Critical Access Hospitals and other community sites. About 46 percent of these sites had clinical trial experience, while 55 percent were new to research. Sites that need help launching and sustaining research programs can access resources through an integrated partnership with Elligo Health Research®.

Conclusion

"The opportunities have never been better. People have been committed to this for a long time, so what is different now? First, the leadership at the relevant federal agencies is making this a priority, starting with FDA. The Centers for Medicare & Medicaid Services have made clear they want to see movement in the direction of advanced primary care centered on people rather than fragmented and driven by fee-for-service, and that makes measurable and substantial progress on improving health equity outcomes, especially after the pandemic. But it's going to take leaders who are connected with organizations on the ground or connected with frontline health providers and the work that you're doing to support research now to help make sure this really translates."

Mark McClellan
Director, Duke-Margolis Center for Health Policy

FasterCures is encouraged that a healthy marketplace is growing to enable more community-based research, with many emerging ideas and interesting models for sponsors, health systems, and their partners to engage more diverse participants in community settings. We believe, however, that the private-sector research ecosystem would benefit from the creation of an alliance or coalition to serve as a precompetitive forum for sharing best practices and taking collective action on common challenges to drive toward an ecosystem in which:

- Community hospitals, health centers, and provider practices have access to the personnel, resources, and technology they need—whether embedded internally or connected externally—to engage in research that is meaningful to the people they serve.
- Research sponsors coordinate and collaborate—rather than compete—to build capacity in community sites, and public- and private-sector research sponsors are better aligned in their efforts.
- Community sites and their partners have access to a sustainable pipeline of research opportunities so they can maintain their commitment and skills as well as build trust with their constituents.
- Technology platforms and data collection are better standardized and harmonized, are minimally burdensome to sites and staff, and contribute to improved outcomes for communities.

Federal investment and policy can serve as drivers for private-sector investment and coordination. Federally funded research infrastructure and trials support many of the same sites utilized by private-sector research sponsors and have built robust models of community research engagement. FDA guidance regarding how to achieve more representative trial populations is guiding a strong focus by the private sector on community engagement. Government can provide evidence to support the return on investment of engagement as well as improvements in key performance indicators.

Clinical trials networks, as evidenced during the pandemic, really are "national critical infrastructure." As a result, collaboration and information-sharing between the public and private sectors are essential to maintaining and expanding standing research capacity and its readiness—between public health emergencies and for the benefit of all citizens.

"It is an all-of-us approach in order for us to make a dent on this issue and in order for us to see the kind of ecosystem that ideally we want patients to be connected to."

Esther Krofah
Executive Vice President for Health, Milken Institute

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About the Milken Institute

The Milken Institute is a nonprofit, nonpartisan think tank focused on accelerating measurable progress on the path to a meaningful life. With a focus on financial, physical, mental, and environmental health, we bring together the best ideas and innovative resourcing to develop blueprints for tackling some of our most critical global issues through the lens of what's pressing now and what's coming next.

About FasterCures

FasterCures, a center of the Milken Institute, is working to build a system that is effective, efficient, and driven by a clear vision: patient needs above all else. We believe that transformative and life-saving science should be fully realized and deliver better treatments to the people who need them.

About the Authors

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Kristin Schneeman is a senior director at FasterCures, having joined FasterCures in April 2005 with primary responsibility for its innovation portfolio of projects and activities, focused on best practices in the funding and conduct of medical research and innovative collaborations among players in the research enterprise. She brings to FasterCures decades of experience in public policy, politics, academia, and the media. Schneeman served for three years as a senior adviser and policy director to a gubernatorial candidate in Massachusetts, as a policy aide to a US Congressman, and for four years as the frontline manager and chief-of-staff for a senior adviser to Vice President Al Gore. At Harvard University, she directed research projects on future challenges facing governments and on complex negotiations in business, politics, and international relations. Schneeman began her career as a producer of documentary films, for which she was the recipient of an Emmy Award in 1990. Schneeman received a BA from Bryn Mawr College in 1987.