MILKEN INSTITUTE

OCTOBER 2025

Access Point:

Trends in Clinical Trials Transformation #1

Introduction

Each quarter, FasterCures conducts a horizon scan to examine the ways in which emerging trends, organizations, and initiatives are innovating to address clinical trial access and efficiency. We then publish *Access Point* briefs that highlight breakthrough technologies, regulatory and industry advancements, and innovative partnership models that are shaping the future of clinical research. For new clinical research market entrants and their established health ecosystem partners, a brief provides the strategic intelligence needed to navigate an evolving clinical trial landscape and translate insights into meaningful research impact.

Clinical Trial Access and Efficiency

Access to clinical trials is vital to both patients and the medical research enterprise, but geographic and socioeconomic barriers significantly impede participation and reduce trial efficiency. Milken Institute research indicates that clinical trial sites in the US are not always close to high-prevalence patient populations and that counties with lower income levels and higher rates of disability are more likely to be at least 60 miles from a trial site. The clinical research industry faces mounting pressure to address distance as an obstacle to trial access and to accelerate drug development timelines while containing costs, because the average clinical trial now takes over six years to complete, and costs can exceed $40 million for a late-phase study. *Access Point* highlights how innovations in trial conduct are addressing dual challenges of trial access and operational efficiency, shaping the future of more streamlined, cost-effective clinical research that better serves both patients and sponsors. This *Access Point* brief explores four key themes: trial trends, power in big data, connections to care, and industry and regulatory priorities.

Trial Trends

Mapping Market Entrants

Lengthy patient recruitment timelines and the increasing complexity of clinical trial protocols are driving the adoption of artificial intelligence (AI)-enabled solutions to match patients with trials. This past spring, MassiveBio and Flatiron announced a strategic partnership to leverage their AI platform and research infrastructure, respectively, to accelerate patient identification and recruitment for clinical trials. This partnership is only one new offering for sponsors, contract research organizations (CROs), and their partners, but it reflects the increased investment in and focus on new approaches to address the patient recruitment bottleneck.

Even the federal government is investing dollars to address this persistent problem. Earlier this year, the National Institutes of Health (NIH) launched TrialGPT, a proof-of-concept system that leverages large language models to match patients efficiently with suitable clinical trials. In early tests, the system decreased patient screening time by 43 percent.

In another recently announced partnership, Komodo Health, a health-care data and analytics company, and Nasdaq plan to help hedge funds, private equity, venture capital firms, and other market participants monitor dynamic health-care and pharmaceutical industry trends through the newly created Nasdaq Medical Claims Insights (NMCI) dataset. NMCI will enable market participants to forecast drug- and company-level revenues, analyze shifts in market shares, and identify emerging drugs and companies—thereby driving smarter investment through real-world insights. The dataset is the first to offer such granular health-care market intelligence to investors and indicates a strong interest in the use of composite data on patient journeys to inform health-care decision-making.

Bringing Trials Closer to Home

A recent study by the Tufts Center for the Study of Drug Development indicates that patients and trial sites are highly receptive to direct-to-patient (DtP) shipping of investigational treatments, which can reduce the administrative burden of trial participation and promote treatment adherence. Increased trust and investment in DtP shipping will help to expand and accelerate trial enrollment, reduce attrition, and enhance the patient experience. The study also explores challenges related to technical support, logistics, and patient instructions for participation in trials that use DtP.

Power in Big Data

Launching AI Agents for Clinical Research

IQVIA and NVIDIA announced the launch of multiple orchestrator agents, all trained on IQVIA life sciences data, to expedite clinical research. The AI agents are designed to manage

and accelerate target identification, trial site start-up, and clinical data review for IQVIA's pharmaceutical customers. The data review agent, in particular, uses a set of automated checks to catch data issues early, reducing the data review process from seven weeks to as few as two weeks. The use of these AI agents is expected to fundamentally transform indication prioritization and study timelines, and thereby reduce time to insights and boost therapeutic access for patients.

Growing Patient and Caregiver Access to Digital Health Data

A recent data brief from the assistant secretary for technology policy (ASTP) at the US Department of Health and Human Services indicates that patient access to online medical records has more than doubled in the past decade, with 65 percent of individuals accessing their patient portal in 2024 compared to 25 percent in 2014. Proxy or caregiver access to patient portals more than doubled between 2020 and 2024, from 24 percent to 51 percent, demonstrating the utility of health data access for caregivers and care coordinators who help patients to optimize their care. App-based access to online medical records increased significantly, from 38 percent in 2020 to 57 percent in 2024, while web-only access declined from 60 percent to 42 percent over the same period. In 2024, more than half of individuals (59 percent) had multiple online medical records or patient portals, yet only 7 percent used portal-organizing apps to combine information from different portals. This discrepancy highlights a greenfield opportunity to better consolidate digital tools to drive coordinated care and better understanding of health status.

With direct access to comprehensive health data through patient portals and health apps, patients can more fully understand their medical history, current conditions, and treatment timeline. With complete access to test results, diagnoses, and medication histories, patients and their providers can more accurately assess their eligibility for relevant studies—empowering them in their own treatment and potentially enabling more research opportunities.

Reducing Barriers to Open Data Access for Trials

Clinical trial conduct is becoming increasingly dependent on timely access to electronic health record (EHR) data for patient recruitment and monitoring. Several health-care start-ups whose products depend on timely access to EHR data have filed lawsuits against major EHR vendors that could have ripple effects on the use of big data and AI technology to support clinical trial operations. The lawsuits allege violations of the 21st Century Cures Act by restricting data access, with one company citing difficulties obtaining real-time treatment data crucial for its AI-powered clinical tools. Although the EHR vendors claim compliance with data-sharing laws, their proprietary systems could make it expensive and difficult for competitors to access the patient information essential for technology-enabled trials. The dispute highlights broader challenges around data interoperability in health care, as federal agencies signal intentions to

promote more open data standards that could facilitate clinical research innovation through ASTP's Trusted Exchange Framework and Common Agreement.

Connections to Care

Modernizing Nonemergency Medical Transportation to Boost Trial Access

Lack of reliable transportation is a significant barrier to clinical trial participation, especially for rural and under-resourced communities served primarily by Medicaid. App-based rideshare companies, such as Lyft and Uber, are reducing transportation insecurity to enable higher-volume, more diverse trial participation. Health systems, CROs, and their partners can arrange courtesy rides for trial participants through a web-based application or a direct application programming interface (API) overlay, to address nonemergency medical transportation (NEMT) needs. More than 28 states, representing 78 percent of Medicaid members, have incorporated Lyft into their Medicaid NEMT programs to provide services within a Medicaid network of 57 million people. These services have helped some end-users dramatically reduce no-show rates for routine care and exceed industry benchmarks for representative enrollment in trials by 300 percent.

Expanding Trial Access Through Retail Pharmacy Networks

Retail pharmacies in the US continue to strengthen decentralized clinical trial capabilities by leveraging existing health-care touchpoints to reduce barriers to enrollment and increase trial efficiency and diversity. For example, the Decentralized Clinical Operations for Healthcare and Research (D-COHRe) partnership between Walgreens and the US Biomedical Advanced Research and Development Authority (BARDA) enables real-world evaluation of medical countermeasures. Announced in late 2024, the partnership offers an at-the-ready clinical trial platform for activation during public health emergencies and an opportunity for BARDA to address priority research questions through diverse and efficient nonemergency trials.

Questions remain about the status and sustainability of the partnership amid the acquisition of Walgreens by private equity firm Sycamore Partners, BARDA's proposed merger with the Advanced Research Projects Agency for Health (ARPA-H), and uncertainty about some of BARDA's contracts. These structural shifts, in both the private and public sectors, are set against a backdrop of dramatic reductions in the federal funding for biomedical research-related efforts more broadly.

Exits from the Connected Care Marketplace

Best Buy has exited the decentralized trial and hospital-at-home market with its sale of Current Health. The sale comes on the back end of slower-than-expected adoption of at-home health

care, despite initial optimism about technology to support distributed care four years ago when Best Buy acquired Current Health. The acquisition followed the passage of the Centers for Medicare & Medicaid Services' Acute Hospital Care at Home waiver program, which reduced mortality and spending, but will expire in September 2025 without an extension from Congress.

Industry and Regulatory Priorities

Trends in Clinical Trial Activity and Therapeutic Focus Areas

The number of trial starts has stabilized to pre-pandemic levels after two years of decline, as total pharmaceutical company expenditures for research and development continue to increase. According to *IQVIA's Global Trends in R&D 2025 Report*, the top four disease areas for trial starts—oncology, immunology, neurology, and cardiovascular—combined accounted for 71 percent of trial starts in the past year.

Regulatory Resources

- Food and Drug Administration (FDA) National Priority Voucher program promises expedited drug review in 1-2 months
- Highly anticipated FDA draft guidance on AI in clinical trials provides an assessment framework for AI model credibility
- The Inflation Reduction Act's Drug Price Negotiation Program creates ripple effects across the clinical research landscape

About Us

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.

Milken Institute Health develops research and programs to advance solutions in biomedical innovation, public health, healthy aging, and food systems.

The Milken Institute's FasterCures 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.