



The First and Last Mile: Primary Care

On April 23-24, 2025, the Duke Clinical Research Institute (DCRI) brought together cross-disciplinary experts representing health systems, academia, regulatory agencies, funders, industry, and patients to discuss the importance of and strategies to engage primary care providers and practices in clinical research. Integrating clinical research into U.S. primary care practices offers a valuable opportunity to drive innovation and strengthen the real-world impact of future healthcare advances. The Think Tank sought to both understand how clinical research (including clinical trials) has been effectively implemented into primary care and envisioned how the integration of clinical research into primary care could be expanded and strengthened. Effective clinical research in primary care will require investment in infrastructure and workforce development, research models that foster collaboration between primary care and research teams, diversified funding strategies, health system support, and study designs tailored to address clinically relevant questions that advance primary care practice and improve patient health outcomes.

KEY TAKEAWAYS AND THEMES:

- **Primary care practice has evolved** significantly over the last several decades through marketplace consolidation, adaptation to team-based care, integration of new payment models, development of on-demand care models such as pharmacy-based clinics, and recent technological disruptions. This evolution has created new opportunities to meaningfully engage primary care in clinical research, particularly by leveraging new technologies (e.g., unified medical records, telehealth, and artificial intelligence) to reach primary care patients with reduced overhead costs and improved trial efficiency.
- **Primary care is well suited to evaluate treatments, diagnoses, and implementation approaches for problems present in primary care.** As primary care is often the front line for establishing diagnoses, clinical research should engage primary care to conduct research that will advance care for both common and rare disease states. Moreover, trust between primary care providers (PCPs) and their patients is a key factor for successful recruitment and retention that could enhance participation in future clinical research.
- **Engaging and supporting PCPs to participate in clinical research requires infrastructure support.** Existing primary care-focused practice-based research networks (PBRNs) with centralized, experienced research teams linking to satellite clinic sites may minimize the burden on individual primary care practices' engagement in research. Technological supports may also facilitate decentralized yet supported primary care research networks. This PBRN infrastructure should invest in developing and nurturing longitudinal clinical research relationships to establish trust between primary care sites and the clinical research ecosystem.
- **Identifying appropriate clinical trial designs for primary care is essential to success.** Historically, quality improvement, phase IV, and implementation trials have leveraged primary care and while not all clinical trials will fit well into primary care settings, there is potential to move beyond post-approval studies in the primary care setting. To enhance feasibility, trials in primary care should be designed to integrate seamlessly into the primary care practice workflow, considering factors like technology support and the specific needs of patients and clinicians. These pragmatic trials in primary care provide the added benefit of delivering real-world evidence to evaluate therapeutic effects in a more generalizable patient population.
- **A shortage of primary care researchers and PCPs available to engage in primary care research already exists.** Developing training and support programs to encourage trainees and PCPs to engage as primary care researchers is essential to expanding the ability to conduct clinical trials in primary care. These programs have previously been built into wider PBRN funding and could tap into PCPs' interest to engage in clinical research to advance their patients' care.
- **Clinical trials in primary care settings can bring value to patients, clinicians, health systems, payers, and industry partners.** Understanding the perspectives of these different partners and the value proposition of research for each group can help inform trial designs and research questions to ensure that they are relevant and beneficial to each involved partner. Patients and providers may benefit from personal and professional satisfaction, financial supports, and academic engagement (especially for provider promotion in academically affiliated practices). This is balanced with potential barriers for participation through possible disruptions in clinical care delivery, financial practice models, regulatory burdens, and the potential for lost patient trust through industry partnership or perceived clinical experimentation with patient care.

ACTIONABLE ITEMS

Develop the Primary Care Research Infrastructure:

- Build trust with clinical partners through trial co-design with clinical teams and patients via the formation of representative clinician and patient advisory boards.
- Utilize existing and emerging clinical technologies (e.g., electronic health records, centralized data repositories, artificial intelligence, and wearables for ambulatory monitoring) to enhance trial efficiency, reduce redundancy and wasted time, and facilitate cost savings.
- Establish partnerships with underutilized health care partners to expand primary care clinical trial reach (e.g., pharmacies and urgent care centers).
- Embed research training opportunities for trainees and clinical staff in trials to expand the network of available primary care researchers for future clinical trials in primary care.
- Invest in existing organizational resources, like PBRNs, to centralize research supports, cultivate clinical research expertise, build trust, maximize efficient clinic site/patient recruitment through clinic champions, and minimize primary care clinic and clinician burdens.

Identify Novel Funding Sources:

- Develop public-private partnerships among government agencies (federal and state), payers, health systems, foundations, and industry to fund future primary care clinical research through a sustainable research infrastructure that addresses relevant scientific questions and aligns with the strategic and economic interests of funding partners.
- Create and disseminate protocols for multi-sector engagement and efficient partnership with primary care, clinical research teams, and funders to facilitate financial partnerships to drive the expansion of clinical research in primary care.

Design Clinical Trials Appropriate for Primary Care:

- Design studies that incorporate principles of quality by design or fit-for-purpose, community-engaged research, human centered design, dissemination and implementation science, pragmatic clinical trials, or embedded sub-studies within larger clinical trials.
- Trial designs should utilize new technologies and integrate seamlessly into primary care practice workflows to minimize clinical practice site burden, maximize the potential for primary care-based patient recruitment, and account for implementation challenges associated with moving from controlled trials to real world environments.

For more information, please visit <https://dcri.org/insights-and-news/insights/dcri-think-tanks>.