



OPEN LETTER FROM HEALTH SYSTEMS AND THEIR PARTNERS COMMITTED TO BETTER EVIDENCE | NOVEMBER 9, 2021

Advancing Clinical Trials at the Point-of-Care: Building a Platform to Give Patients and Clinicians Needed Evidence for Better Care

Today, we are announcing a new collaboration to help our patients and enable our clinicians to access the evidence they need to deliver the best care. The Advancing Clinical Trials at the Point-of-Care coalition (ACT@POC) is bringing together health systems, community-based care organizations, health research organizations, and other collaborators to support the design and conduct of adaptable and responsive clinical trials focused on increasing participation, improving patient access, and facilitating development of targeted therapies with important impact on patient outcomes.

The conduct of clinical trials in the U.S. has grown increasingly complex, often disconnecting them from over-burdened clinicians. Further, the promise of electronic records and digital health apps that help connect us directly to patients has not translated into frictionless data collection in a way that accelerates trial participation. An inadequately optimized regulatory landscape and the lack of access for most patients to well-designed trials limits clinical trial diversity and evidence generation.

The impact of these issues on evidence generation is easy to see. In the pandemic, only a small fraction of U.S. COVID patients was able to participate in clinical trials, and only five percent of those trials were designed in a way that was likely to have an impact on clinical practice, making it difficult to determine quickly whether many existing treatments, such as hydroxychloroquine or convalescent plasma, were beneficial. Despite the growing availability of cancer treatments, evidence remains limited on the best combination therapies for many patients. While new treatments for Alzheimer's disease are coming, or approved, many questions remain about which types of patients respond to these therapies, or how much effect these drugs may have on improving functional status and quality of life, compared to other interventions. Further, the trial size requirements, and high average cost of conducting a trial for a cardiovascular drug, as well as the lack of incentives to support trial conduct result in few cardiovascular studies taking place to bring new treatments to market or help us understand how to better use the treatments we have.

Congress and federal agencies have taken steps to improve clinical trial capacity and effectiveness. The National Institutes of Health (NIH) implemented the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) initiative, which is investigating several promising COVID-19 therapeutics using innovative trial designs. However, due to a complex set of issues, some of the most practical and community-based ACTIV trials have not achieved broad and diverse patient participation. It is critical to connect these well-intentioned efforts to more effective engagement of health systems and practicing providers, well beyond the academic setting.

ACT@POC seeks to complement those efforts and address these challenges. The ACT@POC coalition will identify practical steps to implement well-designed, large-scale clinical trials that meet patients where they are – in the community, at the point of care with their clinicians. The coalition is committed to changing the culture of participation in trials in a variety of clinical settings.

ACT@POC will support larger-scale, more efficient clinical trials by:

Engaging practicing clinicians in a broader range of care settings, to obtain much greater clinical trial participation, so research will reflect large and diverse patient populations who are typically less represented in clinical research.

Supporting the development and adoption of tools that enable straightforward data collection from electronic data systems used to support and improve routine clinical care, to limit the burdens and maximize the benefits for practicing health care workers.

Collaborating with clinical trial design leaders, regulators, funders, sponsors, and other stakeholders **to assure that clinical trial design features are fit for purpose**—with relatively simpler design and data collection requirements for products where mechanisms and safety issues are better understood.

Supporting the enrollment of diverse trial participants through broader participation in effective trials. The lack of representation in clinical trials continues to magnify health disparities. Without sufficient representation, optimal prevention, diagnosis, and treatment decisions cannot be made.

Enhancing an existing and emerging platform trials in areas of unmet need (i.e., registry-based trials that assess multiple therapeutics simultaneously) to enable meaningful, large-scale trials that maximize learning from patient participation and minimize burden on participating hospitals, clinicians, and patients while collecting adequately reliable data.

Improving technology supports and capabilities to conduct large-scale studies over time, enabling increasingly streamlined trial participation and supporting care improvement.

This initiative is more urgent than ever. Health care providers are trying to emerge from the deep challenges of the COVID-19 pandemic, including its evidence gaps. More promising treatments than ever are in development and within reach of entering the market, but without the amount of evidence patients and their clinicians need to know how to use them effectively. It's time for a change, and we are committed to finding solutions that leverage the promise of digital health and biomedical innovation so that evidence generation translates into impact for patients and fulfills the potential of a learning health system that reaches all Americans.

Sincerely,

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