ACT@POC

Committed to Better Evidence and Better Care

Advancing Clinical Trials at the Point of Care Coalition: FAQs

What is the Coalition for Advancing Clinical Trials at the Point of Care?

Advancing Clinical Trials at the Point of Care coalition (ACT@POC) aims to fill critical gaps in the quality and timeliness of evidence on the safety and effectiveness of therapeutics, by bringing clinical trials to the point of care for a much broader range of clinicians and patients. The ACT@POC Coalition will support trials that work for frontline clinical practices on key questions that matter to these clinicians and their patients. This effort will include:

- the development and diffusion of digital health tools that make clinical trials simpler to run and more accessible to patients;
- collaborative work to engage policymakers in addressing key barriers to frontline participation while generating quality evidence and assuring patients are informed and engaged; and
- partnering with clinical trial networks and product developers to enable faster, less costly, and more inclusive trials.

This multi-stakeholder effort will help the clinical trial enterprise answer priority research questions, prepare for future public health emergencies, and address key gaps in making progress on reducing burden and improving health equity for common chronic diseases.

Who is part of the Coalition?

The Coalition comprises not-for-profits, health care organizations and academic institutions. At launch, the coalition includes:

- Duke Margolis Center for Health Policy
- MITRE
- Mayo Clinic
- CURE Drug Repurposing Collaboratory (C-Path + NCATS + FDA)
- Duke University Health System
- Intermountain Healthcare
- Emory University Morningside Center for Innovative and Affordable Medicine
- University of California Irvine
- Broad Institute of Harvard and MIT

How will this coalition be funded?

The Coalition is supported by in-kind contributions from its members and the Margolis Family Foundation through the Duke-Margolis Center for Health Policy. The Coalition intends to pursue funding from independent foundations and federal agencies, as well as support from the clinical trials in which its members participate.

What's the first research project? When will you have findings to report? Will you be publishing in medical journals?

ACT@POC is currently exploring lead opportunities for expanding clinical trial participation, in such areas as:

- **cardiovascular disease**—where new product introduction has declined and outcomes are worsening;
- **pandemic preparedness**—where there is strong interest in applying lessons learned from COVID-19 to broaden participation in meaningful trials, building on successes like the RECOVERY Trial;
- **common cancers**—where questions exist about the right combination of treatments for particular types of patients; and
- **neurodegenerative diseases**—where a growing number of products may be coming to market soon, with key questions remaining about their effective use and impact in routine clinical practice.

The Coalition aims to partner with clinical trial networks and product developers to speed evidence development through putting its approach into practice. We expect any Coalition-supported trials to follow best practices for independence, transparency, and publication of results.

The COVID-19 pandemic, alongside worsening health trends and health disparities, has underscored the need for accelerated, collaborative research at the point of care, especially to engage traditionally underrepresented populations. The tools and approaches developed by the Coalition are likely to be applicable to a wide range of clinical areas where evidence is limited by the cost and absence of broad participation in clinical trials.

What are the challenges facing clinical trials that ACT@POC intends to address?

The complexity and cost of traditional clinical trials pose obstacles to broader provider and patient participation and make it more difficult to find effective treatments for diseases.

Clinical trials have been separated from patient care, with extensive treatment protocols, separate and extensive data collection requirements, and well-intentioned regulatory requirements that make it very difficult for busy clinicians and their patients to participate. As a result, especially for common conditions that make up the bulk of disease burdens in the United States, trials typically don't include diverse practice settings, making it very difficult for most patients to participate in trials. The lack of representative populations and the high cost per patient of participating means that many trials that could provide valuable evidence to frontline clinicians and their patients simply aren't undertaken.

The consequences of inefficiencies and the limited value of much clinical research have been apparent in the COVID-19 pandemic. An analysis found that, of the 2,610 trials of existing COVID-19 therapeutics registered on clinicaltrials.gov by December 1, 2020, only 5% had sufficient enrollment and/or other key design features that would enable the generation of definitive results about treatment efficacy.[1] Few of the trials conducted for COVID-19 therapeutics are likely to yield actionable evidence.

The same is true for evidence generation to address common chronic diseases with high health and economic burdens. For example, the size requirements and average cost of a cardiovascular drug trial, as well as the lack of incentives to support trial conduct, make it so that few such studies are taking place to bring new treatments to market or to help us understand how to better use the treatments we have.

How will the coalition address these challenges?

ACT@POC will bring experience, resources, and expertise in working with frontline clinicians on addressing key clinical research questions with the goal of making clinical trials easier to join and more accessible to patients. Coalition members also intend to back up this effort with their collective ability to influence the direction of clinical research in the United States, so that clinical trial evidence will be better and cheaper, and frontline health care will improve. Our initial work includes a number of specific steps to improve clinical trials:

- **Develop and implement digital tools**: Digital technology is transforming our ability to obtain and integrate data, and to reach and engage trial participants, and it has begun to have an impact on making clinical trials easier. Coalition members have been leading these efforts and intend to build on them. This will include efforts to spread the adoption of digital tools in a range of areas to broaden participation and reduce data collection costs, including reliable automated data collection from electronic medical records and other sources, better opportunities to validate and expand common data models, and improvements to consent and enrollment supports.
- **Engage with policymakers to solve challenges** in trial regulation and broad trial network support – including ways to assure informed consent and patient engagement in busy frontline practices; advancing trial designs that are both effective and feasible in frontline settings; and accelerating the adoption of trial financing and payment methods that are better suited to networks that support frontline engagement.
- **Identify, partner with, and enhance existing and emerging clinical trial networks** that can make rapid progress on implementing effective practical trials for common health problems and public health emergencies - limiting the need for new networks.
- In conjunction with progress on clinical trial design and implementation, **support culture change in health systems**, by collaborating with providers and payers to increase participation and representativeness – creating a learning health care system that supports quality care that keeps getting better.

[1] Bugin K, Woodcock J. Trends in COVID-19 therapeutic clinical trials. *Nature Reviews Drug Discovery*. 2021;20(4):254-255. doi:10.1038/d41573-021-00037-3

What makes the Coalition different from other clinical trial efforts?

ACT@POC isn't a clinical trial network – it's a coalition driven by health care providers to make clinical trial networks more effective and representative by helping them succeed in a much broader range of clinical practice settings. ACT@POC is an invitation for clinical trial supporters and product developers to partner in solving the urgent problems of clinical trial cost and representativeness – and is a commitment by health care providers across the country to assure that we make progress faster.

The ACT@POC Coalition will partner to drive the implementation of large-scale clinical trials to address priority evidence questions in the real-world clinical settings that provide care to the vast majority of the US population. The coalition will develop recommendations, alongside technical assistance products, and digital health tools to support enhanced clinical trial capacity that will provide a much-needed complement to existing trial networks and facilitate evidence generation to address timely "real-world" research questions in diverse populations and health care settings.

The coalition effort aims to complement and build on existing trial networks in two primary ways:

- **ACT@POC will engage practicing clinicians** in support of research that integrates with routine care— the coalition will work with clinicians in a broader range of care settings, especially in community settings, to obtain much greater clinical trial participation so research reflects large and diverse patient populations who are not typically able to participate in clinical research. To do this, the coalition will provide centralized site activation and data collection resources and will partner to develop streamlined trial protocols that limit the need for extensive data collection and support research that generates answers to questions that practicing clinicians care most about.

- **ACT@POC will work with regulatory partners, payers, and other stakeholders** to support decision-grade evidence generation through partner trial networks that meets shared evidentiary needs and standards. The coalition will work to develop a strategic framework for evidence generation that maps existing research network capacity with information needs. The coalition will also identify gaps in existing trial network capacity and make consensus recommendations about improvements to the regulatory oversight and data collection infrastructure to ensure trial conduct that is non-burdensome, scientifically robust, and fit-for-purpose in decision-making.