



ISSUE SPOTLIGHT

Clinical Trial Innovation

Emerging from the COVID-19 pandemic, Duke-Margolis identified a need for more practical and more equitable clinical evidence generation to enhance clinical care.

Harnessing technology and policy innovation to target these challenges is a bold goal, which requires collaboration across sectors. Duke-Margolis collaborates with many leaders in this space, including government, academic, industry, and health system partners, to achieve a shared vision.



The clinical research enterprise has evolved greatly over the past several decades, with a clear need for evidence-based policy analyses and solutions to better marry clinical care and research, and to address longstanding access barriers that continue to limit representative access to trials for hardly reached populations. Duke-Margolis is expanding the clinical trials focus in important areas:

- With a coalition of health care leaders. Duke-Margolis and Duke Clinical Research Institute (DCRI), together with partnering health systems, established the Coalition for Advancing Clinical Trials at the Point-of-Care (ACT@ POC) to address the gaps in timely evidence to inform patient care.
- By putting ideas into action. DCRI and Duke-Margolis are embarking on a project to inform both policy and practice, ultimately improving our understanding of obesity treatments and modern equitable clinical trial conduct.
- Through regulatory policy and FDA collaboration. Duke-Margolis and FDA will work to identify opportunities to clarify regulatory policy to enable innovative methods and operational approaches while maintaining standards in compliance with Good Clinical Practice.
- Through Centers for Medicare & Medicaid Services (CMS) and payer collaboration to advance learning health systems. Duke-Margolis and CMS are collaborating on a series of roundtables to provide more infrastructure and support for learning health system activities.
- Through an emphasis on representativeness in clinical trials. Ensuring that research is conducted in groups representing the diversity of the American population is critical to effectively translate research findings to clinical practice. Duke-Margolis is conducting a project focused on exploring challenges to achieve representativeness and synthesizing best practices.

Advance Our Work

More support for this portfolio would enable the Duke-Margolis team to proactively lead a dynamic, international conversation on how to improve evidence generation. Funding would enable additional projects to explore policy, infrastructure, operational, financial and cultural barriers to point-of-care trials and innovative trial-based evidence generation approaches. The Duke-Margolis team would continue our thought leadership putting forward recommendations and considerations for improvement. Duke-Margolis and ACT@POC partners also could support more point-of-care trial demonstration projects to build increased confidence in these trial approaches and address identified barriers in real trials.