

Critical Questions for Pragmatic Clinical Trialists: Insights From the NIH Pragmatic Trials Collaboratory's First Decade

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This workshop, which will take place over 2 half-days, will explore questions that are critical to designing and implementing pragmatic clinical trials (PCTs) conducted within health care systems. Pragmatic trials differ from traditional more-explanatory clinical trials, as they test interventions or practices delivered in real-world settings. The NIH Pragmatic Trials Collaboratory has now been supporting PCTs for a decade, including a set of trials in the PRISM (Pragmatic and Implementation Studies for the Management of Pain to Reduce Opioid Prescribing) program of the Helping to End Addiction Long-term[®] Initiative, or NIH HEAL Initiative[®]. This workshop is an opportunity to glean the most salient lessons learned from an experienced group of PCT investigators who will openly share the challenges they have encountered, solutions they have developed, and thoughts for the future.

The NIH Pragmatic Trials Collaboratory has launched 22 PCTs that are conducted within a variety of U.S. health care systems—with over 1,000 clinical sites. These trials have served as case studies for addressing challenges of pragmatic research, and the program has developed an extensive set of methods and best practices for PCTs. As the NIH portfolio of PCTs expands, it is increasingly prudent to share knowledge about the keys to success for designing and implementing such trials within health care systems. Many research processes for PCTs have improved over the past decade due to strategies developed by trailblazing PCT investigators and their collaborators in the NIH Pragmatic Trials Collaboratory. Sharing insights from a broad spectrum of PCTs represented by this group can help continue the research transformation.

The workshop will include a series of moderated discussions that focus on critical questions for the design and conduct of successful PCTs. Case examples from the NIH Pragmatic Trials Collaboratory and the PRISM program will be shared to illustrate lessons learned. Topics will include changes and current best practices regarding the use of electronic health records for pragmatic research, considerations for PCT study design, how to optimize a 1-year planning phase for a PCT, and tips for implementing interventions in complex health systems. Perspectives and experiences shared by the NIH Pragmatic Trials Collaboratory investigators may be used to bolster the success of future PCTs, which can contribute to improving care delivered to underserved populations, addressing health disparities in clinical care, and achieving health equity by implementing evidence-based care.