

MEETING SUMMARY | APRIL 20-21, 2020



BACKGROUND

Master protocol studies investigate multiple diseases, multiple therapies, or both.¹ Despite a growing enthusiasm for the use of master protocol studies – particularly in light of the COVID-19 pandemic – expertise is critically limited and few resources exist to guide planning and implementation.

Following a productive Expert Meeting in October 2019 as part of its Master Protocols work, CTTI developed several publically-available resources aimed at driving the appropriate and efficient use of master protocols in diverse therapeutic areas.



MEETING OBJECTIVES

CTTI's second master protocol expert meeting aimed to:

- Refine CTTI resources to support the development of emerging master protocol studies in diverse therapeutic areas
- Identify specific capacity building efforts to support cross-institutional collaboration in response to COVID-19 and other major public health threats



MEETING THEMES

- **Master protocols offer a viable solution.** They foster coordination, collaboration, and communication during clinical research – all of which are needed in the fight against COVID-19 and future pandemics.
- **Working together remains a challenge.** Major barriers related to effective collaboration across disparate efforts still need to be addressed. Having open discussions, sharing experiences and data, and aligning trials could help to ease this challenge.
- **We have a solid start.** Feedback on draft CTTI resources was largely positive. Suggested enhancements included to incorporating more real-world examples to clarify application, create companion educational resources that are targeted to meet specific stakeholders' needs, and consider the unique needs and challenges of various settings and studies.

¹Woodcock, Janet, and Lisa M. LaVange. "Master Protocols to Study Multiple Therapies, Multiple Diseases, Or Both." *The New England Journal of Medicine* 377.1 (2017): 62-70. Web. Jan 17, 2019.



NEXT STEPS

CTTI is currently working to:

- Enhance its draft resources, incorporating feedback from the Expert Meeting and a public open comment period.
- Publically announce the final resources this summer.
- Continue to explore efforts to drive the appropriate use of master protocol studies, in light of COVID-19 and beyond.



ADDITIONAL RESOURCES

- **Meeting materials**, including agenda, participant list, and presentations
- Read more about CTTI's **Master Protocols Project**



ABOUT THE CLINICAL TRIALS TRANSFORMATION INITIATIVE (CTTI)

The Clinical Trials Transformation Initiative (**CTTI**), a public-private partnership co-founded by Duke University and the FDA, seeks to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. Bringing together organizations and individuals from across the enterprise CTTI is transforming the clinical trials landscape by developing evidence-based solutions to clinical research challenges.



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