

MEETING SUMMARY | OCTOBER 22-23, 2019



BACKGROUND

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

CTTI is developing a roadmap for the successful design and implementation of master protocol studies through its Master Protocol Studies project. Through a series of expert meetings, CTTI will develop tools and resources aimed at driving the appropriate and efficient use of master protocols in diverse therapeutic areas.



MEETING OBJECTIVES

CTTI's first master protocol expert meeting aimed to:

- Identify strategies, tools, and resources to drive appropriate and efficient use of master protocols;
- Define potential solutions for common roadblocks to master protocol design and implementation across the pre-planning, planning, and execution phases; and
- Using the draft high-level roadmap developed by CTTI as a starting point, discuss creation of a broad set of tools and resources that can drive adoption of master protocols across diverse therapeutic areas.



MEETING THEMES

- **The Value is Clear...** Master protocol studies are growing in popularity. Their flexible design and highly centralized operational features have the potential to more efficiently ask and answer scientific questions.
- **...But a Roadmap is Needed...** However, many organizations lack experience in running master protocol studies, presenting major study design and operational challenges.
- **...As is Support for Non-Traditional Drug Developers.** Publicly available resources are needed to support organizations that want to design a master protocol trial, particularly for non-traditional drug developers such as patient advocacy groups and other nonprofits.
- **Be Excited, but Realistic.** Enthusiasm for a master protocol approach should be balanced with awareness of its complex infrastructure, long-ranging timelines, and significant upfront planning and resources.
- **There are Keys to Long-Term Success.** A strong cross-institutional infrastructure, including a robust site network and solid communications approach, are critical to achieving long-term sustainability of master protocols.

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 will review materials, strategies, and tools discussed at the meeting to work on next steps, including:

- Revising the existing roadmap
- Identifying working groups to help further progress this project
- Prioritizing and creating the first draft tool(s)
- Planning for the next expert meeting



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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