The Fastest Path to Effective COVID-19 Treatments: Using Master Protocol Studies

Agenda of the Master Protocol Public Summit held January 13, 2021

CTTI MISSION: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials

MEETING OBJECTIVE:

As we've learned in the global pandemic, the faster we have reliable answers, the better. And as we look to successfully accelerate progress for COVID-19 treatments, master protocol studies can provide a solution. This summit will offer approaches to fast track the quest for COVID treatments by accelerating enrollment into master protocols while the pandemic is still raging and vaccinations are ramping up.

Mission: To develop and drive adoption of practices that will increase the quality and efficiency of clinical trials.

With an independent voice, FasterCures is working to build a system that is effective, efficient, and driven by a clear vision: patient needs above all else. We believe that transformative and life-saving science should be fully realized and deliver better treatments to the people who need them.

The Center's Mission is to improve health and the value of health care through practical, innovative, and evidence-based policy solutions.

JANUARY 13, 2021

10:30 a.m. ET — **Welcoming Remarks**

Pamela Tenaerts, Executive Director, CTTI

10:35 a.m. ET — **Opening Comments**

Janet Woodcock, Operation WarpSpeed
The Need for Actionable, Reliable COVID 19 Treatment Trials

10:42 a.m. ET — **Current State of COVID Clinical Trials: A Call to Action**

Robert Califf, MD, MACC,
Head of Clinical Policy and Strategy, Verily and Google Health

Objectives:

- Provide an overview of U.S. COVID-19 treatment clinical trials registered on ClinicalTrials.gov
- Call for more coordinated clinical trials conduct and scaling of current master protocols for COVID-19

10:55 a.m. ET — **Practical Solutions to Setting Up Master Protocol Sites**

Objectives:

- Examine key challenges to starting up new sites including contracting, competing trials, staffing, and IRB submission
- Discuss potential solutions to overcome these hurdles

Panelists:
Derek Angus, REMAP-COVID
Laura Esserman, I-SPY-COVID
Manizhe Payton, ACTIV-2

Moderator: Pamela Tenaerts, CTTI

Panel Discussion

11:15 a.m. ET — **Increasing Participant Enrollment in Master Protocols**

Objectives:

- Examine key challenges limiting participant enrollment including competition with other trials, burden on staff
- Discuss potential solutions to overcome hurdles such as co-enrollment

Panelists:
Dan Cooper, UC Irvine
Martin Landray, RECOVERY trial
Kousick Biswas,Veterans Health Administration

Moderator: Esther Krofah, FasterCures, a center of the Milken Institute

Panel Discussion

11:35 a.m. ET **Lessons for the Future**

Objective:

- Discuss changes needed to ensure rapid and efficient trial infrastructure is ready for this and future pandemics
- Discuss approaches to increase clinical trial engagement of practicing clinician investigators in community settings thereby ensuring representative clinical trials
- Discuss approaches to decreasing duplication and increasing coordination, including on compound and endpoint selection, across the clinical trial enterprise to support efficient evidence generation

Panelists:
Samuel Brown, Intermountain Health System
Adrian Hernandez, PCORnet
Saye Khoo, AGILE

Moderator: Mark McClellan, Margolis Center for Health Policy

Panel Discussion

11:55 a.m. ET **Closing Comments**

Pamela Tenaerts, Executive Director, CTTI

For more information, contact Project Manager Kathy Jooss or visit http://www.ctti-clinicaltrials.org.