Rare Diseases Forum

Conducting Clinical Trials Amid COVID-19 (Rapid Action Group)
Web Discussion II
July 9, 2020 1:00-2:00pm ET

Moderator:
Veronica Miller, PhD, Executive Director, Forum for Collaborative Research

Topics of Discussion:

- How has the pandemic and lock-down affected the overall health of clinical trial participants and how do we account for this in the analysis?
- How do we account for the pandemic in trial analysis?
    - What is the estimand in question that we want to address?
- Does the new FDA Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency provide adequate guidance for trials in rare diseases? If not, what is missing?

Introduction
Veronica Miller, PhD, Executive Director
Forum for Collaborative Research

Concerns Surrounding Conducting Clinical Trials
Satrajit Roychoudhury, PhD, Mstat, Senior Director or Statistical Research and Data Science Center at Pfizer
Jerry Vockley, MD, PhD, Director for the Center for Rare Disease Therapy/ Chief of Medical Genetics - University of Pittsburgh
Peter Mesenbrink, Ph.D., Executive Director of Biostatistics, Novartis Pharmaceuticals Corporation

Open Discussion
Veronica Miller, PhD, Moderator and Call Participants

Closing Remarks/ Next Steps
Veronica Miller, PhD, Executive Director
Forum for Collaborative Research