Advancing Therapeutic Development for COVID-19 Treatment: Part One
Thursday, November 2nd, 2023

National Union Building
918 F St NW, Washington, DC 20004

AGENDA

8:00 AM	**Registration & Breakfast**	
9:00 AM	**Introductory Remarks**	
	Welcome and Introductions	*Veronica Miller, Forum for Collaborative Research* *John Farley, US Food and Drug Administration* *Stephanie Buchholz, European Medicines Agency**
	Session I: Characterizing Risk Factors for Severe COVID-19 to Inform Participant Eligibility Criteria for Enrollment	
	Moderator: Veronica Miller, Forum for Collaborative Research	
9:15 AM	***Part A: Define Patient Populations***	
	Introduction	*Benjamin Lorenz, US Food and Drug Administration*
	COVID-19 Epidemiology	*Pragna Patel, Centers for Disease Control and Prevention*
	Understanding Risk of Progression to Severe COVID-19: Lessons from a Large Integrated Health System	*Jacek Skarbinski, Kaiser Permanente*
	The Impact of COVID-19 Treatments on Patient Outcomes: A Probabilistic View Based on the National COVID Cohort Collaborative (N3C)	*Bradley Price, West Virginia University*
	Severe Outcomes of COVID-19 Among Increased-Risk Adults	*Scott Dryden-Peterson, Brigham and Women's Hospital*
11:30 AM	**Break**	
11:45 AM	***Part B: Possible Trial Designs for Targeted Populations: Issues and Feasibility***	
	Ethical Considerations for Non-hospitalized Patients with COVID-19	*Benjamin Lorenz, US Food and Drug Administration*
	Panel Discussion	*Stephanie Buchholz, European Medicines Agency** *Jeffrey Murray, Forum for Collaborative Research* *Jose Pablo Morales, US Food and Drug Administration* *Scott Dryden-Peterson, Brigham and Women's Hospital* *Michael Boeckh, Fred Hutchinson Cancer Center** *Kai Lin, Aerium Therapeutics**
1:00 PM	**Lunch Break**	
1:30 PM	**Session II: Possible Trial Endpoints and Medically Attended Visits**	
	Moderators: Sally Hodder, West Virginia University* and *Jeffrey Murray, Forum for Collaborative Research	
	Medically Attended Visits (MAVs): Is it Time to Expand the Primary Endpoint for Trials in Participants with Mild-to-Moderate COVID-19?	*Aimee Hodowanec, US Food and Drug Administration*
	Effect of Nirmatrelvir/Ritonavir vs Placebo on COVID-19-Related Hospitalizations and Other Medical Visits	*Edward Weinstein, Pfizer*
	Considerations for Medically Attended Visits in COVID-19 Clinical Trials	*Carisa De Anda, Merck*
	Panel Discussion	*Aimee Hodowanec, US Food and Drug Administration* *Stephanie Buchholz, European Medicines Agency** *Edward Weinstein, Pfizer* *Carisa De Anda, Merck* *Ann Kwong, Kwong Pharma Consulting LLC* *Annie Luetkemeyer, University of California San Fransisco**
4:30 PM	**Concluding Remarks**	
	Next Steps	*Veronica Miller, Forum for Collaborative Research* *Jeffrey Murray, Forum for Collaborative Research* *John Farley, US Food and Drug Administration* *Stephanie Buchholz, European Medicines Agency**
5: 00 PM	**Adjourn and Evening Reception**	

***** Indicates remote participation