

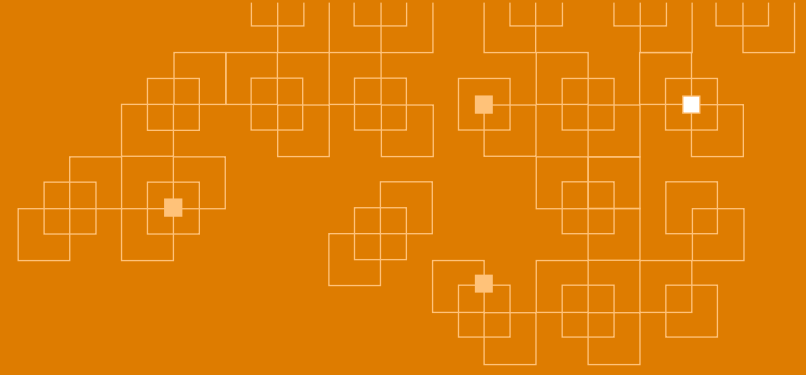
THE FORUM
For Collaborative ResearchSM

Advancing Therapeutic Development for COVID-19 Treatment 1

Washington, DC

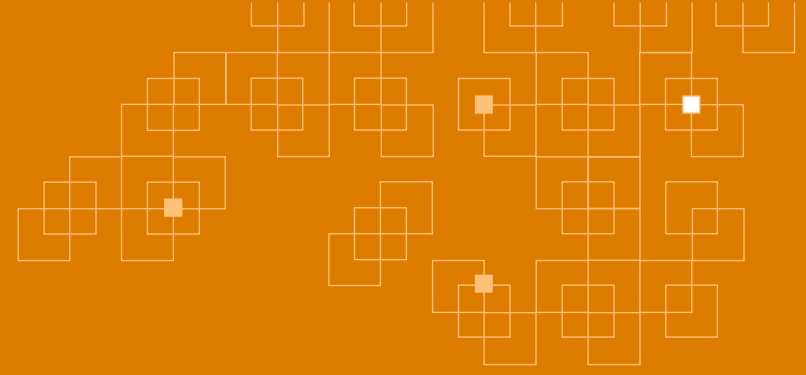
Thursday, November 2, 2023

Berkeley Public
Health



Introductory Remarks

Veronica Miller, *Forum for Collaborative Research*



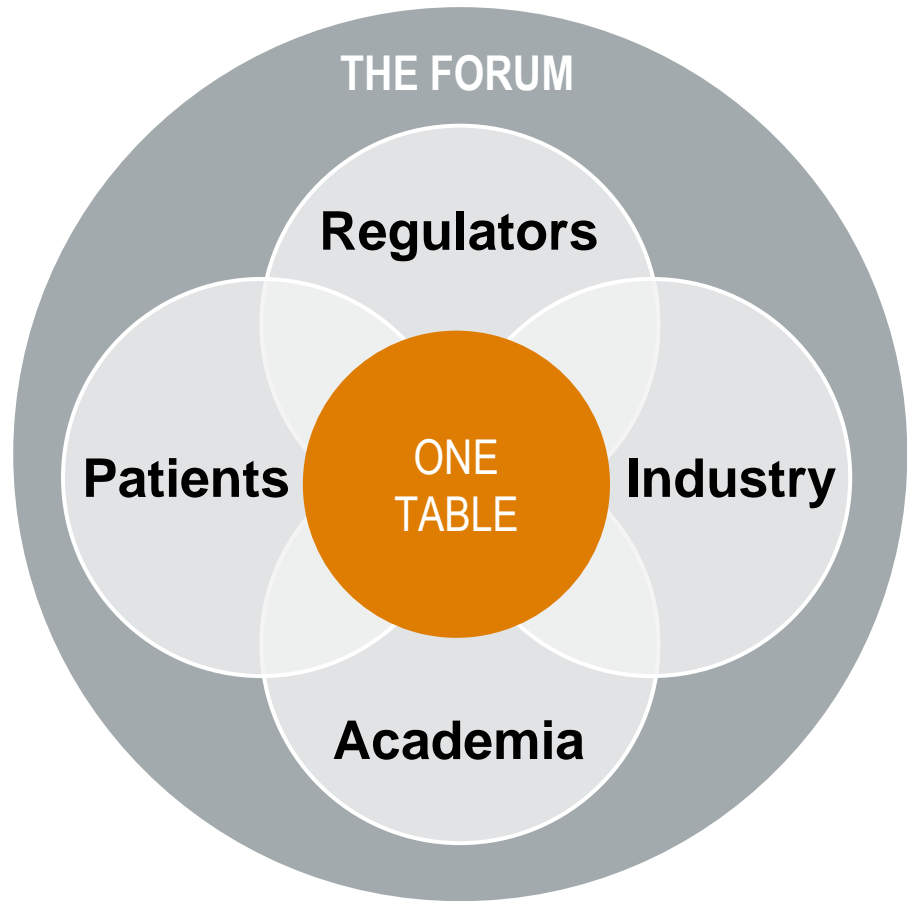
Forum Overview

Overview of The Forum

- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for various diseases
- **How:** provide a neutral, independent, safe space for discussion and deliberation across stakeholder groups
 - Focus on developing consensus, increasing synergy and collaboration, and reducing duplication and uncertainty
 - Ongoing working group activity throughout the year anchored by larger project events
 - Active & engaged participation



The Forum's Concept



Increase Efficiency

Decrease Uncertainty

- Enhanced clarity
- Innovation
- Collaboration

- Redundancy
- Development time
- Risk

Forum Operating Principles

- Independent and neutral venue
 - Ongoing multi-stakeholder dialogue
 - Each stakeholder group has an equal voice
- Facilitate best science-based decisions, in real time
 - Break down inefficiencies and redundancy
 - Increase clarity, collaboration and innovation
 - Benefit to whole field, especially patients

Forum = Safe Space

- Closed meeting
 - No marketing
 - No press
- Bring your expertise
 - Leave your “hat” at the door

Rules of the Room and Zoom



What's said in the room, stays in the room

What's said in the room, is not for attribution

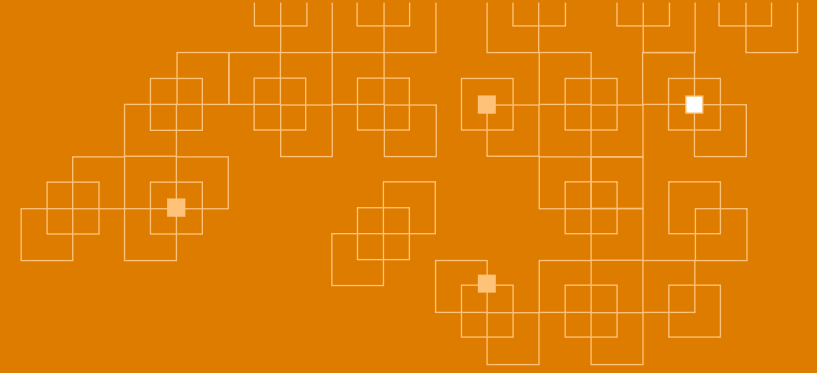
Let the science speak

Active participation

Forum Team



- Veronica Miller – Director
- Christopher Berry – Events Manager
- Donnice Butler – Senior Administrative Assistant
- Nicholas Murdock – Research Associate
- Mitchell Leus – Research Associate
- **Shilpa Mitra – Research Associate**
- Logan Donaldson – Research Associate
- Sehyr Khan – Research Associate
- Azza Karrar – Senior Research Associate
- Alicia Jellinek – Program Financial Analyst
- Chris Hoffman – IT and Operational Director
- Margot Yann – Lead Data Scientist
- Zachary Rooney – Research Associate
- Sammy Berman – Research Data Analyst
- Robin Schaefer – Post-Doctoral Researcher
- **Jeffrey S. Murray – Program Advisor**
- John Sninsky – Program Advisor
- Alessi Ayvaz, Undergraduate Student Researcher



Project Overview and Agenda

Overview of the COVID-19 Project



- Given current high rates of natural and vaccine-mediated immunity, a trial endpoint relying only on hospitalization and/or death may no longer be practical
- There remains populations with unmet medical need for broadly active therapeutics that can prevent and treat COVID-19
- Series of meetings will convene stakeholders to strategize on establishing acceptable trial designs, control arms, and clinical and/or surrogate virologic endpoints for future COVID-19 therapeutic drug development

Part 1: Meeting Agenda



- **Session 1: Characterizing Risk Factors for Severe COVID-19 to Inform Participant Eligibility Criteria for Enrollment**
 - Part A: Define patient populations based on risk of progression to severe COVID-19 and describe baseline risk factors
 - Part B: Ethical considerations for non-hospitalized patients with COVID-19
- **Session 2: Possible Trial Endpoints and Medically Attended Visits**
 - Medically Attended Visits (MAVs): Is it Time to Expand the Primary Endpoint for Trials in Participants with Mild-to-Moderate COVID-19?