



**THE FORUM**  
For Collaborative Research<sup>SM</sup>

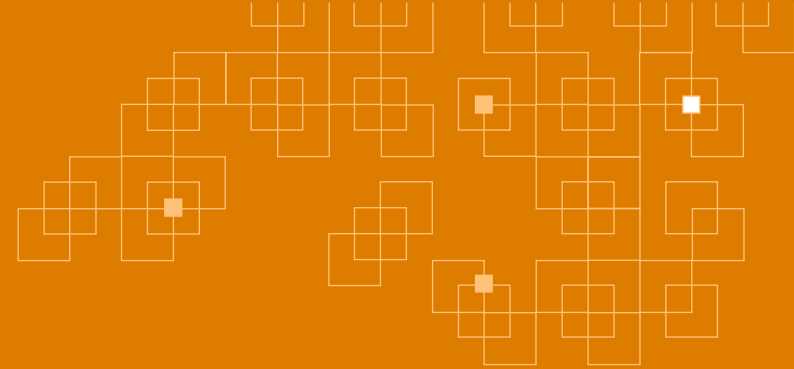
# Ocular Diseases Forum 1

Los Angeles, CA

May 15, 2023

Veronica Miller, PhD  
Director

**Berkeley** Public  
Health

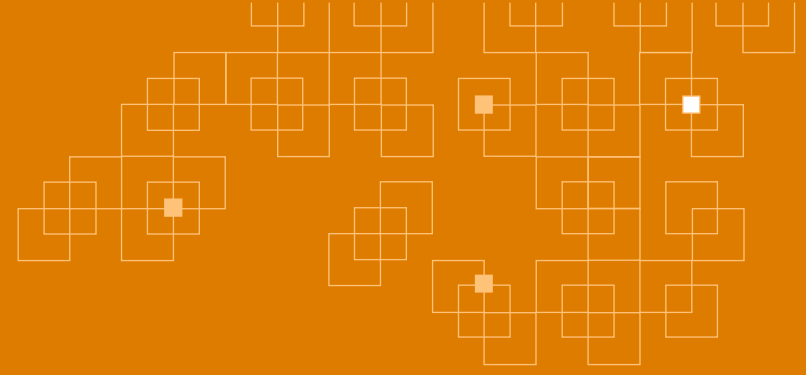


# Welcome & Introduction

Claire M. Gelfman

Veronica Miller

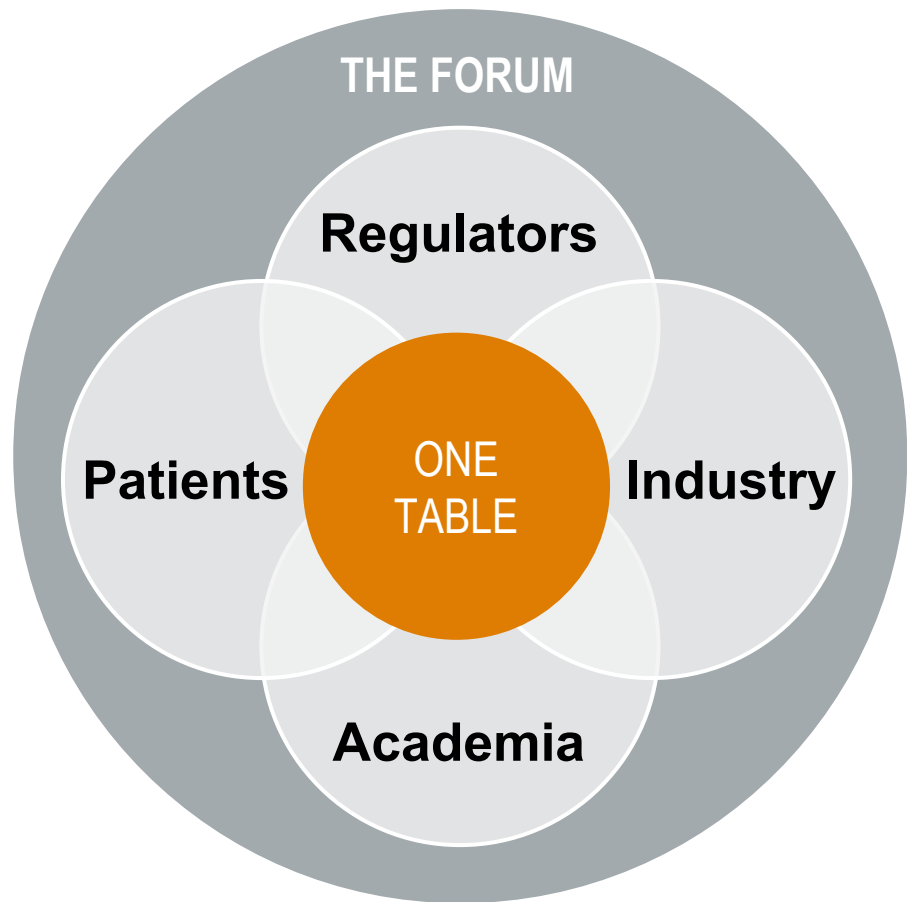
Jim Wang



# Governance & Forum Process

Brenda Rodriguez

# The Forum's Concept



Increase Efficiency

Decrease Uncertainty

- Enhanced clarity
- Innovation
- Collaboration
  
- Redundancy
- Development time
- Risk



**“Starting with HIV, the Forum consistently and effectively applies the multi-stakeholder model to advance the development path for new treatments in multiple disease areas.”** Eric A. Hughes, MD, PhD, Senior Vice President, Clinical Development and Translational Medicine, Vertex Pharmaceuticals

# Characteristics

- Non-competitive
- Safe environment
- Independence
- Neutrality
- Transparency
- Information democracy
- Synergy vs duplication
- Equal voice

## The traditional process:

Single sponsor  
communicating  
independently  
with single  
regulatory agency

- VS -

## The Forum process:

All sponsors  
communicating  
at the same  
time with multiple  
regulatory agencies



**“The Forum brings together stakeholders from around the globe with cross-Atlantic and -Pacific perspectives to reduce interagency discordance.”**

Laurent Fischer, MD, CEO, Adverum Biotechnologies

- Advance development of regulatory strategies
  - Evolving science and evolving consensus
- Generate evidence through collaboration
  - Efficient use of data
- Provide mechanism for patient-centered drug development
- Provide mechanism for innovation in data use and analytics
- Networking Opportunities



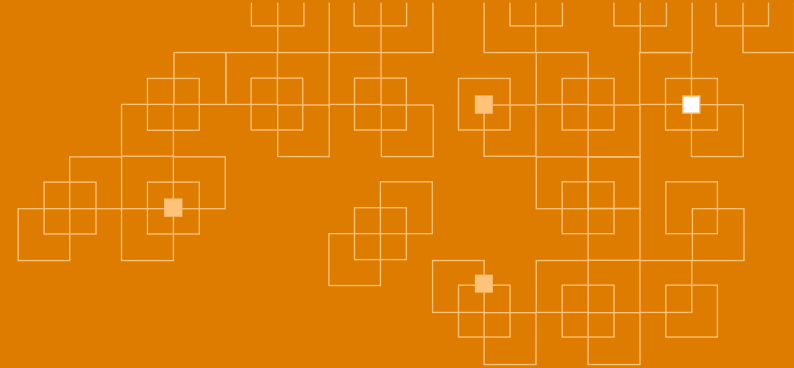
**“The Forum addresses cutting edge regulatory science and policy issues with proven results.”**

George Hanna, MD, VP Infectious Diseases Global Clinical Development, Merck & Co., Inc.

# Forum Team



- **Veronica Miller – Director**
- **Brenda Rodriguez – Deputy Director**
- Logan Donaldson – Research Associate
- Azza Karrar – Senior Research Associate
- **Sehyr Khan – Research Associate**
- Mitchell Leus – Research Associate
- Shilpa Mitra – Research Associate
- Nicholas Murdock – 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
- Jeffrey S. Murray – Program Advisor
- John Sninsky – Program Advisor
- Nayri Alajaji, Graduate Student Researcher
- Mayland Treat, Graduate Student Researcher



# Goals & Objectives

Sehyr Khan

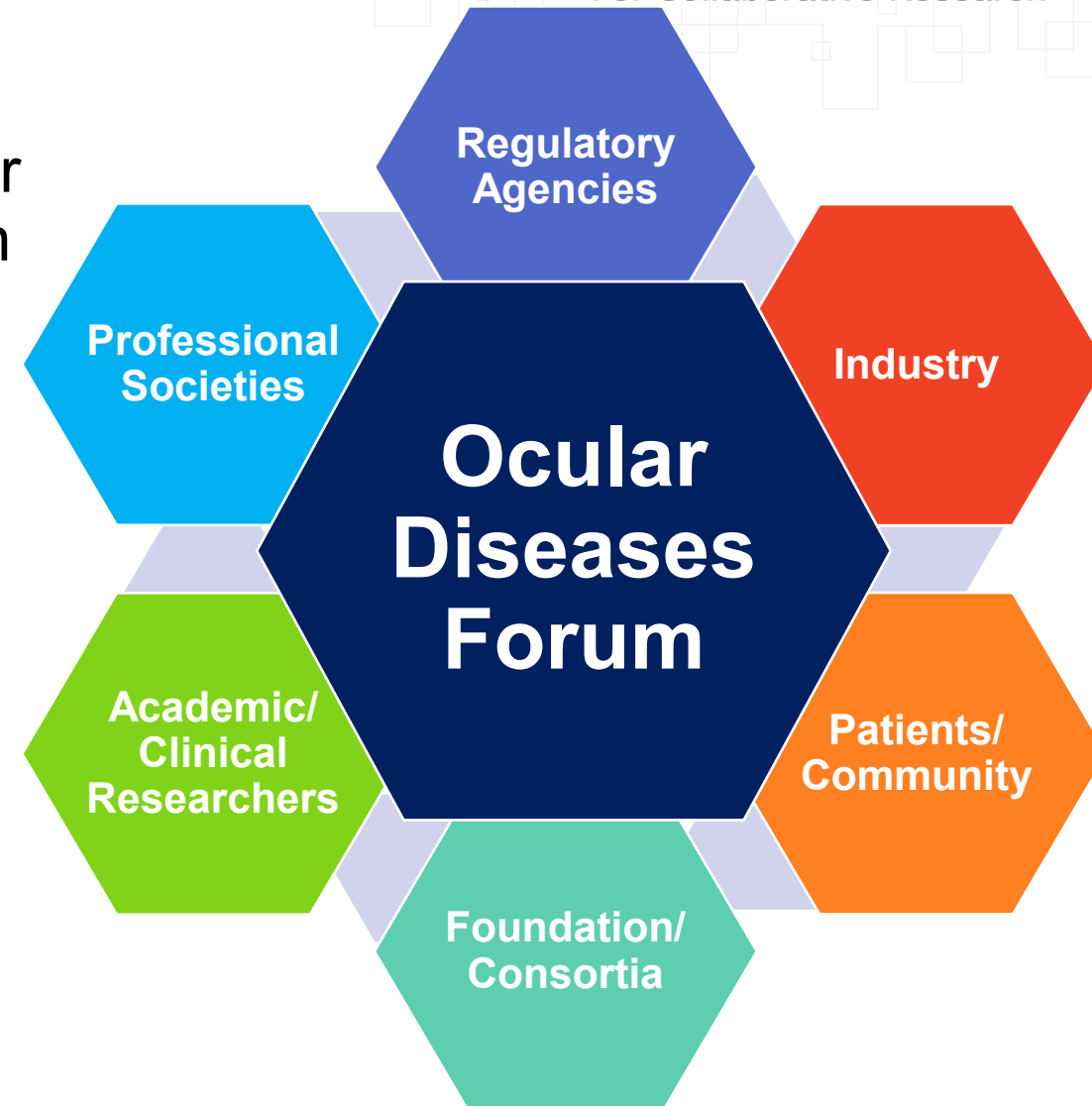


# Overview of the Ocular Diseases Forum

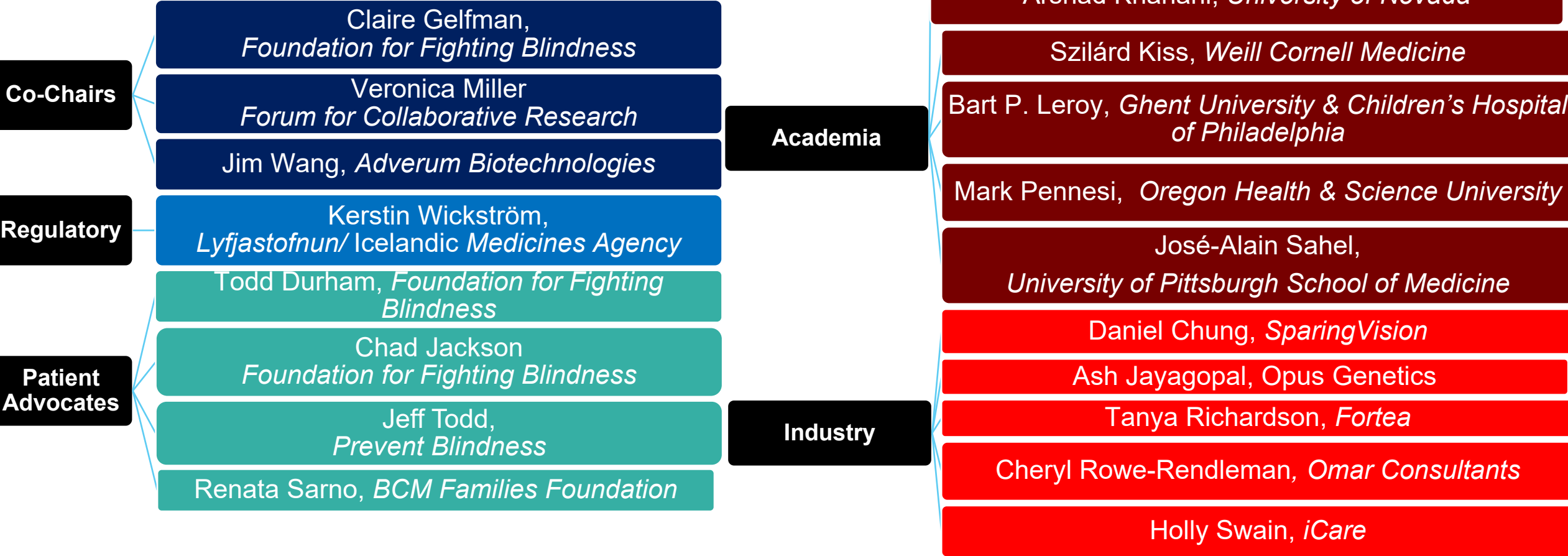


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- **What:** a platform for ongoing multi-stakeholder dialogue to identify barriers, prioritize research and identify solutions to accelerate therapeutic development for IRDs/wet-AMD
- **How:** provide a neutral, independent, safe space for discussion 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



# Steering Committee



Ocular Diseases Forum Sponsors

**ADVERUM**

 **Fortrea**

**icare**  
For better perception

# 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**

# Goals and Objectives for Today



1. The Global Regulatory Landscape
2. Identifying Gaps and Barriers Developing clinically meaningful endpoints for different types of vision loss
3. PROs and PROMs
4. Patient Perspective
5. Preview New Working Groups
  - a. Outcomes and deliverables will include increased clarity and publication of working group outputs.

# Outcomes & Deliverables



- 1. Working Groups:** recommendations, position papers, reports, manuscripts for submission to peer-reviewed journals based on discussions
- 2. ODF1:** peer-reviewed publication reporting consensus on present issues in the regulatory path based on ODF1 discussions