



Innovation in Drug Research and Development for Prevalent Chronic Diseases — A 3-Part Virtual Workshop

February 22, March 1, and March 8, 2021

Half of all Americans live with at least one chronic disease, such as heart disease, cancer, stroke, or diabetes. These and other chronic diseases are the leading cause of death and disability in the United States and are a leading driver of health care costs. Yet investment in the leading causes of death and disability, other than cancer, has not kept pace with the public health need. This virtual public workshop will provide a venue for stakeholders to examine bottlenecks to innovation in drug research and development (R&D) for prevalent chronic diseases and highlight opportunities for spurring drug R&D in this space.

The virtual workshop will be conducted in three parts:

- Part One (February 22, 2021) will discuss key opportunities and challenges for increasing investment, broadening biospecimen collection and registry use, and supporting innovative discovery and preclinical research in prevalent chronic diseases.
- Part Two (March 1, 2021) will consider key aspects and opportunities related to development, translation, regulation, and support for innovative clinical research in prevalent chronic diseases.
- Part Three (March 8, 2021) will consider case studies in both discovery and clinical research related to prevalent chronic diseases, and discuss potential cross-cutting applications for other prevalent chronic diseases.

For additional information on this virtual workshop, please visit [the main project page](#).

Part 1: February 22, 2021
Opportunities in Discovery and Preclinical Research for
Prevalent Chronic Diseases
11:00 am – 3:00 pm ET

11:00 a.m. **Welcome and Opening Remarks**

CARLOS GARNER, *Workshop Co-chair*
Vice President, Global Regulatory Affairs
Eli Lilly and Company

ANANTHA SHEKHAR, *Workshop Co-chair*
Senior Vice Chancellor for Health Sciences and Dean of the School of Medicine
University of Pittsburgh

SESSION I OVERVIEW OF R&D FOR PREVALENT CHRONIC DISEASES

Session Objectives:

- Discuss the unique cross-cutting challenges facing preclinical research for prevalent chronic diseases; and
- Highlight opportunities to overcome those challenges and mobilize the R&D innovation engine.

11:10 am **A Patient’s Perspective on Mobilizing the R&D Innovation Engine**

RUSS PAULSEN
Chief Operating Officer
US Against Alzheimer’s

SESSION II FUNDING AND INVESTMENT DECISION-MAKING IN DISCOVERY RESEARCH

Session Objectives:

- Examine common causes of failures in discovery research for prevalent chronic diseases and how failures could be avoided or “go/no-go” decisions could be accelerated in the future
- Discuss whether investment and cultural incentives are in alignment for spurring the type of R&D that will address unmet need when it comes to prevalent chronic diseases; and
- Consider the factors that determine which research areas key decision-makers (e.g., investors, sponsors, researchers) decide to move forward.

11:25 am **Response and Overview**

SUSAN SCHAEFFER, *moderator*
President and Chief Executive Officer
The Patients’ Academy for Research Advocacy

- 11:35 am **Funder Perspective**
JASON MELLAD
Chief Executive Officer and Founder
Start Codon
- 11:50 am **Public-private partnership investor perspective**
JOSEPH MENETSKI
Associate Vice President of Research Partnerships
Foundation for the National Institutes of Health
- 12:05 pm **Moderated Panel Discussion and Audience Q&A**
- 12:30 pm **BREAK** (30 mins)

SESSION III BIOSPECIMEN COLLECTION AND REGISTRY USE IN DISCOVERY RESEARCH

Session Objectives:

- Consider lessons learned from other disease areas that could have cross-cutting applications for prevalent chronic diseases; and
- Discuss the availability or need for high quality biospecimen repositories and datasets that represent the patient populations most impacted by prevalent chronic diseases.

- 1:05 pm **Introduction and Overview**
HOWARD B. ROSEN, *Moderator*
Managing Director, BonVelo Ventures
Lecturer, Stanford University
- 1:10 pm **Academic perspective**
ERICA WOODAHL
Associate Professor, Dept. of Biomedical and Pharmaceutical Sciences
University of Montana

SESSION IV NEW TECHNOLOGIES ENABLING DISCOVERY RESEARCH

Session Objectives:

- Discuss the unique cross-cutting challenges in pre-clinical research for prevalent chronic diseases and consider how new technologies could help researchers overcome these challenges; and
- Consider lessons learned from other disease areas for which new technologies have been a key driver of progress.

- 1:25 pm **Academic discovery science-technology perspective**
JOHN NGAI
Director
The BRAIN Initiative, NIH

- 1:40 pm **Artificial intelligence for discovery science**
ANDREW A. RADIN
Chief Executive Officer
twoXAR Pharmaceuticals
- 1:55 pm **Regulator perspective**
QI LIU
Senior Science Advisor, Office of Clinical Pharmacology & Translational Sciences
U.S. Food and Drug Administration
- 2:10 pm **Moderated Panel Discussion and Audience Q&A**
- 2:50 pm **Closing Remarks**

CARLOS GARNER, *Workshop Co-chair*
Vice President, Global Regulatory Affairs
Eli Lilly and Company

ANANTHA SHEKHAR, *Workshop Co-chair*
Senior Vice Chancellor for Health Sciences and Dean of the School of Medicine
University of Pittsburgh
- 3:00 pm **ADJOURN**