The National Academies of SCIENCES ENGINEERING MEDICINE

Forum on DRUG DISCOVERY, DEVELOPMENT, and TRANSLATION

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) discussed 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 2: March 1, 2021
Opportunities in Clinical 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 clinical 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 Journey**
CHRISTIN VEASLEY
Co-founder and Director
Chronic Pain Research Alliance

11:25 am **Mobilizing the R&D Innovation Engine**
CHRONIS MANOLIS
Senior Vice President of Pharmacy
University of Pittsburgh Medical Center Health Plan

SESSION II INVESTMENT AND FUNDING DECISIONS IN CLINICAL RESEARCH

Session Objectives:

- 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 clinical programs key decision-makers (e.g. investors, sponsors, and researchers) decide to move forward.

11:35 am **Economics perspective**
KIRSTEN AXELSEN
Visiting Fellow
American Enterprise Institute

11:50 am **A Payers Perspective: Pricing and Health Economic Drivers that Incentivize Development Investments**
KEN EHLERT
Chief Scientific Officer
United Health Group

12:05 pm **Moderated Panel Discussion and Audience Q&A**

12:25 pm **BREAK** (*30 mins*)

SESSION III INNOVATIVE APPROACHES TO EFFICIENT CLINICAL DEVELOPMENT

Session Objectives:

- Discuss the unique cross-cutting challenges in clinical trials for prevalent chronic diseases (e.g., are the regulatory requirements predictable?);
- Brainstorm and prioritize potential strategies to decrease costs and risks for development (i.e., highlight innovative ways to design clinical trials); and
- Discuss ways to meaningfully engage communities and patients in clinical trials.

1:00 pm **Introduction and overview**
BETTINA DRAKE, *Moderator*
Professor, Washington School of Medicine
Associate Director of Community Outreach and Engagement
Alvin J. Siteman Cancer Center

1:05 pm **Community health researcher perspective**
KAREN WINKFIELD
Executive Director
Meharry-Vanderbilt Alliance

1:15 pm **Industry (regulatory lead) perspective**
MICHELLE ROHRER
Senior Vice President, Global Head of Product Development Regulatory & Policy
Roche

1:30 pm **Regulatory perspective**
JAMES P. SMITH
Deputy Director, Division of Clinical Policy, Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

SESSION IV NEW TECHNOLOGIES ENABLING INNOVATIVE CLINICAL RESEARCH

Session Objectives:

- Discuss the unique cross-cutting challenges in 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 where new technologies have been a key driver of progress.

1:50 pm **Biotech perspective**
GRACE COLÓN
Chief Executive Officer
InCarda Therapeutics

2:05 pm **Regulatory perspective**
ELIZABETH KUNKOSKI
Clinical Methodology Team, Office of Medical Policy
U.S. Food and Drug Administration

2:20 pm **Moderated Panel Discussion and Audience Q&A**

2:50 pm **Closing Remarks**

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Vice President, Global Regulatory Affairs
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3:00 pm **ADJOURN**