The National Academies of
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Forum on Drug Discovery, Development, and Translation
Forum on Aging, Disability, and Independence
National Cancer Policy Forum

Drug Research and Development for Adults Across the Older Age Span

A Virtual Workshop

August 5-6 2020

10:00 a.m. – 3:00 p.m. (ET)

ZOOM WEBINAR REGISTRATION:
https://nasem.zoom.us/webinar/register/WN_1IN7kZ-ESdWppXPNGVPPQw

Agenda

Despite the widespread recognition of the "graying of America," and the need for health care among older adults, there is a dearth of information about the appropriate use of drugs in this population. Older adults are vastly underrepresented in clinical trials. Yet older adults have higher rates of comorbidities and polypharmacy than the general population, and are the majority users of many medications. Additionally, age-related physiological and pathological changes, particularly for adults 80+, can lead to significant differences in the pharmacokinetic and pharmacodynamics of a given drug compared to the general population. There is a void in evidence-based information for making informed decisions on how to best optimize care for older adults, particularly those 80+.

This public workshop will provide a venue for stakeholders to discuss the challenges and opportunities in drug research and development (R&D) for older adult populations, explore barriers that impede safety and efficacy studies in these populations, and share lessons learned for better understanding the clinical pharmacology for 65+ and 80+ populations.

The workshop will feature invited presentations and discussions to:

- Review the current landscape of drug R&D for 65+ and 80+ populations across public and private sectors;
- Consider medication issues for older adult populations (e.g. dosage forms, adherence, polypharmacy, differences in PK/PD);
- Explore methodologies that are currently used or could be implemented to study differences in pharmacology for older adult populations (e.g. minimal sampling);
- Examine barriers to conducting clinical research for 65+ and 80+ populations (e.g. funding, data, co-morbidity, polypharmacy, recruitment, access); and
- Explore approaches to engage 65+ and 80+ populations in clinical research and strategies generate evidence-based information on how to best optimize treatment for older adults.

DAY 1: August 5, 2020

10:00 a.m. **Welcome and opening remarks**
JAMES APPLEBY, *Workshop Chair*
Chief Executive Officer
The Gerontological Society of America

SESSION I INCLUSION OF OLDER ADULTS IN CLINICAL TRIALS: AN EVOLVING LANDSCAPE

Session Objectives:

- Review the current landscape of drug R&D for 65+ and 80+ populations across public and private sectors;
- Consider medication issues for older adult populations (e.g., dosage forms, adherence, polypharmacy, differences in PK/PD);
- Examine barriers to conducting clinical research for 65+ and 80+ populations (e.g., funding, data, co-morbidity, polypharmacy, recruitment, access).

10:10 a.m. **Introduction by session moderator**
JERRY GURWITZ
Executive Director, Meyers Primary Care Institute
Division Chief of Geriatric Medicine, University of Massachusetts Medical School

10:15 a.m. **Knowledge gaps & issues unique to older adults**
ROSANNE M. LEIPZIG
Professor of Geriatrics and Palliative Medicine
Icahn School of Medicine at Mount Sinai

Age-related changes that impact drug metabolism
GEORGE A. KUCHEL
Travelers Chair in Geriatrics and Gerontology, Professor of Medicine
University of Connecticut Center on Aging

Barriers to conducting clinical trials that include older adults
NIH perspective
MARIE A. BERNARD
Deputy Director
National Institutes of Health, National Institute on Aging

Industry perspective
KATHERINE DAWSON
Senior Vice President of the Therapeutics Development Group
Biogen

11:00 a.m. *Moderated panel discussion*

11:30 a.m. **BREAK**

SESSION II CONCOMITANT ILLNESS AND POLYPHARMACY: OVERCOMING KEY BARRIERS

Session Objectives:

- Explore methodologies that are currently used or could be implemented to study differences in pharmacology for older adult populations (e.g., minimal sampling);

11:40 a.m. **Opening remarks by panel moderator**
JONATHAN WATANABE
Professor of Clinical Pharmacy, Associate Dean of Assessment and Quality
University of California Irvine Samueli College of Health Sciences

11:45 a.m. **Clinical trial considerations [Panel]**
Inclusion / exclusion criteria and trial design
HEATHER ALLORE
Professor of Medicine (Geriatrics) and Biostatistics
Yale University

Organ function criteria expansion
STUART M. LICHTMAN
Medical Oncologist
Memorial Sloan Kettering Cancer Center

FDA experience
RAJESHWARI SRIDHARA
Biostatistician Contractor (Retd. Director of the Division of Biometrics V, CDER)
U.S. Food and Drug Administration, Oncology Center of Excellence

Ethics perspective
JASON KARLAWISH
Professor of Medicine
University of Pennsylvania Perelman School of Medicine

12:30 p.m. *Moderated panel discussion*

1:00 p.m. **BREAK**

1:20 p.m. **Opening remarks by panel moderator**
ROBERT TEMPLE
Deputy Center Director for Clinical Science, Office of New Drugs
U.S. Food and Drug Administration, Center for Drug Evaluation and Research

Alternative study approaches [Panel]
Adaptive design
SCOTT BERRY
Co-Founder and President
Berry Consultants

Home-based clinical trials
STEVEN R. CUMMINGS
Executive Director, S.F. Coordinating Center
University of California, San Francisco

Quantitative systems pharmacology models: Mechanistic science perspective
CHRISTINA FRIEDRICH
Chief Engineer
Rosa & Co.

Clinical trial simulation
N. SETH BERRY
Senior Director, Decision Sciences Group
IQVIA

Real world trials
STEVEN CHEN
Associate Dean for Clinical Affairs
University of Southern California School of Pharmacy

2:20 p.m. *Moderated panel discussion*

DAY 1 REFLECTIONS

2:50 p.m. **Closing remarks**
JAMES APPLEBY, *Workshop Chair*
Chief Executive Officer
The Gerontological Society of America

3:00 p.m. **ADJOURN WORKSHOP DAY 1**

DAY 2: August 6, 2020

10:00 a.m. **Welcome and overview of Day 1**
JAMES APPLEBY, *Workshop Chair*
Chief Executive Officer
The Gerontological Society of America

SESSION III THE ERA OF COVID-19 AND BEYOND

Session Objectives:

- Explore methodologies that are currently used or could be implemented to study differences in pharmacology for older adult populations (e.g., minimal sampling);
- Explore approaches to engage 65+ and 80+ populations in clinical research and strategies generate evidence-based information on how to best optimize treatment for older adults.

10:10 a.m. **Opening remarks by panel moderator**
DEBORAH COLLYAR
President
Patient Advocates in Research

10:15 a.m. **Older adult outreach & networking strategies**
JONATHAN TOBIN
President/CEO, Clinical Directors Network (CDN)
Senior Epidemiologist, The Rockefeller University Center for Clinical & Translational Science

Barbershop-based outreach programs: Case study
CIANTEL BLYLER
Clinical Research Pharmacist
Cedars-Sinai Medical Center

Patient perspective
SUSAN STRONG
Director of Patient Engagement
Heart Valve Voice US

Caregiver perspective
LAUREL J. PRACHT
Research Patient Advocate and Patient Representative
NCI Symptom Management and Health-Related Quality of Life Steering Committee

Education for older adults and healthcare practitioners
STEVEN ROTHSCHILD
Professor and Chair, Department of Family Medicine
Rush Medical College

11:15 a.m. *Moderated panel discussion*

11:45 a.m. **BREAK**

12:00 p.m. **Opening remarks by panel moderator, European perspective**
SVEN STEGEMANN
Professor for Patient Centric Drug Development and Manufacturing
Graz University of Technology

Lessons learned from COVID-19
U.S. regulatory changes
HARPREET SINGH
Division Director (Acting)
U.S. Food and Drug Administration, Division of Oncology 2

Infectious disease perspective
JOHN POWERS
Professor of Clinical Medicine
George Washington University School of Medicine

Telehealth / Physician perspective
ERIKA RAMSDALE
Assistant Professor
University of Rochester Medical Center

Digitization of medicine
ERIC TOPOL
Founder and Director
Scripps Research Translational Institute

Patient perspective
BEVERLY CANIN
Patient Advocate
Cancer and Aging Research Group

1:00 p.m. *Moderated panel discussion*

1:30 p.m. **BREAK**

1:45 p.m. **Reflections: Looking forward to the future**

Session moderator
JAMES APPLEBY, *Workshop Chair*
Chief Executive Officer
The Gerontological Society of America

1:50 p.m. AMY ABERNETHY
Principal Deputy Commissioner – Office of the Commissioner
U.S. Food and Drug Administration

ROBERT CALIFF
Head of Clinical Policy and Strategy
Verily and Google Health

MARIE A. BERNARD
Deputy Director
National Institutes of Health, National Institute on Aging

2:20 p.m. *Moderated panel discussion*

2:50 p.m. **Next Steps**
JAMES APPLEBY, *Workshop Chair*
Chief Executive Officer
The Gerontological Society of America

3:00 p.m. **ADJOURN WORKSHOP DAY 2**