ROADMAP TO 2030 FOR NEW DRUG EVALUATION IN OLDER ADULTS

A VIRTUAL WORKSHOP

TUESDAY, MARCH 23, 2021

10:00 AM- 4:30 PM (ET)

WORKSHOP WEBSITE: https://go.usa.gov/xsnrx

REGISTRATION: https://www.eventbrite.com/e/fda-roadmap-to-2030-for-new-drug-evaluation-in-older-adults-tickets-137460709683

OVERARCHING PRINCIPLE: The percentage and clinical profile of older adult patients in clinical trials should represent the target population

Problem: Americans are leading longer and healthier lives than ever before, but older adults often take multiple prescription medications and may be under-represented in pre-marketing drug evaluations. Initial pharmacokinetic/pharmacodynamic studies and later clinical trials to evaluate age-related changes often do not include typical older adults who have multiple chronic conditions and take multiple medications. This can lead to insufficient data on the safety and effectiveness of medications in this population at the time of marketing approval. Data on the safety and effectiveness for new medications likely to be prescribed in typical older adults, especially those at the oldest end of the age span, are critically needed. This workshop will discuss methods to ensure that inclusion of older adults in drug evaluations are representative of the target population for treatment and will also discuss potential strategies to ensure safe and effective drug use in older adults.

The workshop will feature invited presentations and discussions to:

- Review the current regulations and draft guidances for drug evaluation and labeling of medications for older adults
- Review the current data on the inclusion of older adults in clinical trials in selected key therapeutic areas
- Identify the gaps in regulations, guidances, and inclusion of older adults in data collection
- Explore approaches to close the existing gaps

10:00 -10:10 am Welcome and opening remarks
Shiew-Mei Huang, FDA

SESSION I PAST, PRESENT, AND CURRENT STATUS OF GUIDANCES FOR INCLUSION OF DATA ON OLDER ADULTS AND RESULTING ENROLLMENT

SESSION OBJECTIVES:

- Review the history and current guidances for older adults in evaluation of new drugs
- Review the current enrollment of older adults in clinical trials of new drugs in the U.S.
- Review international perspective on enrollment of older adults in evaluation of medications
- Define the problems/gaps

10:10 – 10:15 am Introduction – The Problem Statements by session moderator
Patricia W. Slattum, Virginia Center on Aging

10:15 – 10:40 am History of FDA guidance on drug evaluation in older adult patients
S.W. Johnny Lau, FDA

10:40 – 11:05 am Enrollment of older adults in COVID-19 trials
Sharon Inouye, Harvard

11:05 – 11:30 am EMA perspective on guidance on medicines for older people
Francesca Cerreta, EMA

11:30 – 11:40 am Real-Time Audience Survey 1: Prioritize important gaps in generating knowledge for drug use in older adults

11: 40 am – 12:15 pm Panel Discussion
Moderator: Patricia W. Slattum, Virginia Center on Aging
Francesca Cerreta, EMA
Carolyn Cho, Merck
Jerry Gurwitz, University of Massachusetts Medical School
Sarah Hilmer, University of Sydney, Australia
Bindu Kanapuru, FDA
S.W. Johnny Lau, FDA
Phil Posner, Patient-Centered Outcomes Research Institute Ambassador
Keipp Talbot, Vanderbilt University

12:15 – 1:00 pm LUNCH BREAK

SESSION II THE WAY FORWARD—POTENTIAL SOLUTIONS

SESSION OBJECTIVES:

- Discuss strategies that are currently implementable to fill gaps in knowledge regarding older adults during drug development
- Identify strategies to fill the gap in pharmacokinetic/pharmacodynamic data for older adults
- Identify future strategies to fill the gap in knowledge regarding older adults in drug development and clinical trials of relevant therapeutic areas

1:00 – 1:20 pm	Introduction by session chair *Robert Temple, FDA*
1:20 – 1:45 pm	Clinical pharmacology strategies, FDA perspective *Rajanikanth Madabushi, FDA*
1:45 – 2:10 pm	Pharmaceutical industry perspective *Jack Cook, Pfizer & Sebastian Haertter, Boehringer Ingelheim*
2:10 – 2:25 pm	Lessons learned from pediatric drug development for the older adult community *Gilbert Burckart, FDA*
2:25 – 2:30 pm	BREAK
2:30 – 2:55 pm	An initial step to improve representativeness of older age groups in drug development *Janice B. Schwartz, UCSF*
2:55 – 3:20 pm	What should the framework for older adults be and how to achieve that framework - clinical trials perspective *Robert Califf, Verily and Google Health*
3:20 – 3:30 pm	Real-Time Audience Survey 2: Prioritize the potential next steps based on their impact and feasibility
3:30 – 4:20 pm	PANEL DISCUSSION *Moderator: Robert Temple, FDA* Gilbert Burckart, FDA Robert Califf, Verily and Google Health Jamie Gamerman, FDA Paul Goldsmith, Lilly Rajanikanth Madabushi, FDA Munir Pirmohamed, University of Liverpool, UK Barbara Radziszewska, NIH/NIA/ERP Janice B. Schwartz, UCSF Piet van der Graaf, Certara
4:20 – 4:30 pm	Closing Remarks *Qi Liu, FDA*