# *FDA Perspective: Regulatory Considerations for Treating Older Adults with Cancer*

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# FDA Guidance on Inclusion of Older Adults

| Year | |
|---|---|
| 1997 | Guidance for the Study of Drugs Likely to Be Used in the Elderly (FDA) |
| 2012 | Guidance for Industry: E7 Studies in Support of Special Populations (FDA) |
| 2016 | Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies (FDA) |
| 2016 | Enrollment of Older Adults on Oncology Trials: an FDA Perspective (Journal of Geriatric Oncology) |
| 2017 | Reevaluating Eligibility Criteria – Balancing Patient Protection and Participation in Oncology Trials (NEJM) |

# Content and Format: Geriatric Labeling

- Established in 1997 by the FDA

The “Geriatric use” subsection must cite any limitations on the geriatric indication, need for specific monitoring, specific hazards associated with the geriatric condition, and other information related to safe and effective use of the drug in the geriatric population.

Information on pharmacokinetics related to age, conditions associated with age, and clinical data should be collected and analyzed to learn whether the drug has different effects in older adults. (1997)

"An ***appropriate representation of the geriatric population (including patients with concomitant therapies and co-morbidities) should be enrolled*** in the clinical development program to adequately characterize efficacy and safety in the geriatric population and allow for comparisons with the nongeriatric population. This information would ordinarily be expected in a marketing application." (2012)

"***Where enrollment of geriatric patients has been insufficient despite the efforts of the applicant, a specific plan to collect data postmarketing should be discussed during development and presented in the marketing application." (2012)***

# Enrollment of Older Adults on Oncology Trials: an FDA Perspective (2016)

- Modernizing Eligibility Criteria
  - Promotes greater inclusion of older adults (organ dysfunction)
- Patient Reported Outcomes
  - Provide further information on tolerability of therapy
- Real World Evidence
  - Collaborations with FDA to increase available data on efficacy and safety of novel therapies in older adults

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ASCO SPECIAL ARTICLE

FDA

# Improving the Evidence Base for Treating Older Adults With Cancer: American Society of Clinical Oncology Statement

*Arti Hurria, Laura A. Levit, William Dale, Supriya G. Mohile, Hyman B. Muss, Louis Fehrenbacher, Allison Magnuson, Stuart M. Lichtman, Suanna S. Bruinooge, Enrique Soto-Perez-de-Celis, William P. Tew, Michael A. Postow, and Harvey J. Cohen*

**Table 1.** Recommendation Goals

| Recommendation |
|---|
| To improve the conduct of research |
| Use clinical trials to improve evidence for treating older adults with cancer |
| Leverage research designs and infrastructure for generating evidence on older adults with cancer |
| To improve the research environment |
| Increase FDA authority to incentivize and require research involving older adults with cancer |
| Increase clinicians' recruitment of older adults with cancer to clinical trials |
| Use journal policies to improve researchers' reporting of age distribution and health risk profiles of research participants |

Abbreviation: FDA, US Food and Drug Administration.

# Session 1: Designing clinical trials to include older adults with cancer: Leverage research designs and infrastructure for generating evidence

Moderator: Harvey Cohen, Duke University

Speakers:

Supriya Mohile, University of Rochester Medical Center
Tania Small, Novartis
Hans Wildiers, University Hospitals Leuven

Panelists:

Julia Beaver, U.S. Food and Drug Administration
Jan Buckner, Mayo Institute
Beverly Canin, Patient Advocate
Worta McCaskill-Stevens, National Cancer Institute
Rajeshwari Sridhara, U.S. Food and Drug Administration

# Session 2: Increasing the enrollment of older adults on registration trials to reflect the proportion with the disease: *Strategies and challenges*

Moderator: Heidi Klepin, Comprehensive Cancer Center of Wake Forest University

Speakers:

Bindu Kanapuru, U.S. Food and Drug Administration
Lou Fehrenbacher, Kaiser Permanente
Michaela Popa Mckiver, Bristol-Myers Squibb
Eric Rubin, Merck

Panelists:

Judith Hopkins, Novant Health
Iman Martin, National Cancer Institute
Hyman Muss, UNC Lineberger Comprehensive Cancer Center

# Session 3: Leveraging research designs for real-world patients: Real-world evidence/observational data

Moderator: Harpreet Singh, U.S. Food and Drug Administration

Speakers:

Sean Khozin, U.S. Food and Drug Administration
Gary Lyman, Fred Hutchinson Cancer Research Center
Robert Miller, CancerLinQ

Panelists:

Cynthia Chauhan, FDA Patient Representative Program
William Dale, City of Hope
Gracie Lieberman, Genentech
Yu-Ning Wong, Janssen Scientific Affairs, LLC

# Session 4: Lessons from pediatrics, payers, and the European Medicines Agency

Moderator: Arti Hurria, City of Hope

Speakers:

Peter Adamson, Children's Oncology Group
Susan L. Weiner, Children's Cause for Cancer Advocacy
Donna Messner, Center for Medical Technology Policy
Frans Opdam, Netherlands Cancer Institute

Panelists:

Joseph Chin, Centers for Medicare and Medicaid Services
Rick Pazdur, U.S. Food and Drug Administration
Richard Schilsky, American Society of Clinical Oncology
Margaret Sedenquist, Patient Advocate

# FDA-ASCO
# GERIATRIC ONCOLOGY WORKSHOP

## MONDAY, NOV 6, 2017

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