FDA Perspective: Regulatory Considerations for Treating Older Adults with Cancer

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U.S. Food and Drug Administration
## FDA Guidance on Inclusion of Older Adults

<table>
<thead>
<tr>
<th>Year</th>
<th>Title</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>1997</td>
<td>Guidance for the Study of Drugs Likely to Be Used in the Elderly</td>
<td>(FDA)</td>
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<td>2012</td>
<td>Guidance for Industry: E7 Studies in Support of Special Populations</td>
<td>(FDA)</td>
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<tr>
<td>2016</td>
<td>Evaluation and Reporting of Age, Race, and Ethnicity Data in Medical Device Clinical Studies</td>
<td>(FDA)</td>
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<tr>
<td>2016</td>
<td>Enrollment of Older Adults on Oncology Trials: an FDA Perspective</td>
<td>(Journal of Geriatric Oncology)</td>
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<tr>
<td>2017</td>
<td>Reevaluating Eligibility Criteria – Balancing Patient Protection and Participation in Oncology Trials</td>
<td>(NEJM)</td>
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</tbody>
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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
Improving the Evidence Base for Treating Older Adults With Cancer: American Society of Clinical Oncology Statement


<table>
<thead>
<tr>
<th>Table 1. Recommendation Goals</th>
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<tbody>
<tr>
<td>Recommendation</td>
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<tr>
<td>To improve the conduct of research</td>
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<tr>
<td>Use clinical trials to improve evidence for treating older adults with cancer</td>
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<tr>
<td>Leverage research designs and infrastructure for generating evidence on older adults with cancer</td>
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<tr>
<td>To improve the research environment</td>
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<tr>
<td>Increase FDA authority to incentivize and require research involving older adults with cancer</td>
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<tr>
<td>Increase clinicians' recruitment of older adults with cancer to clinical trials</td>
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<tr>
<td>Use journal policies to improve researchers' reporting of age distribution and health risk profiles of research participants</td>
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</table>

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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#GeriFDA
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