Alliance FOR AGING RESEARCH

Catalyzing Innovation for Healthy Aging

Improving the Evidence Base for Decision Making for Older Adults with Cancer
Patient Advocacy Perspective on Policy Opportunities

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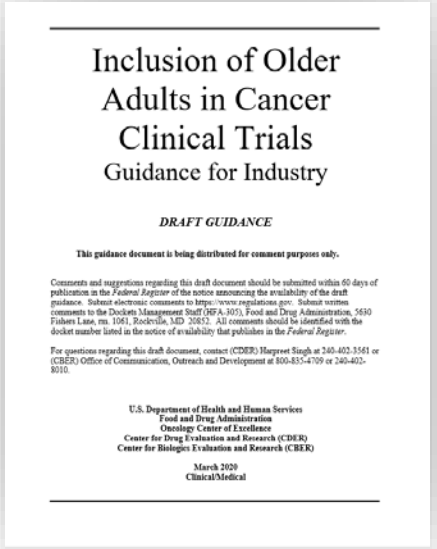
President and CEO
January 25, 2021

Recommendations on FDA Guidance

- Consider recruitment strategies that target community oncologists
- Encourage innovative trial designs that reduce barriers to entry and limitations on specific populations (e.g., adaptive)
- Include the full range of research designs outlined in the FDA's broader "Enhancing the Diversity of Clinical Trial Populations" guidance, finalized November 2020
- Ensure the collection of geriatric and aging biology data with geriatric assessment tools
- Provide more detail about developing and reporting on age sub-groups to capture biological age
- Require the publication of post-market studies on older patients so that clinicians and the public can also benefit from the additional knowledge
- Add specialists in geriatrics and geriatric oncology to the FDA Oncology Center for Excellence; and
- Issue a similar agency-wide guidance for all medical products meant to treat conditions that primarily impact older adults.



Inclusion of Older Adults in Cancer Clinical Trials

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Harpreet Singh at 240-402-3561 or (CBER) Office of Communication, Outreach and Development at 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

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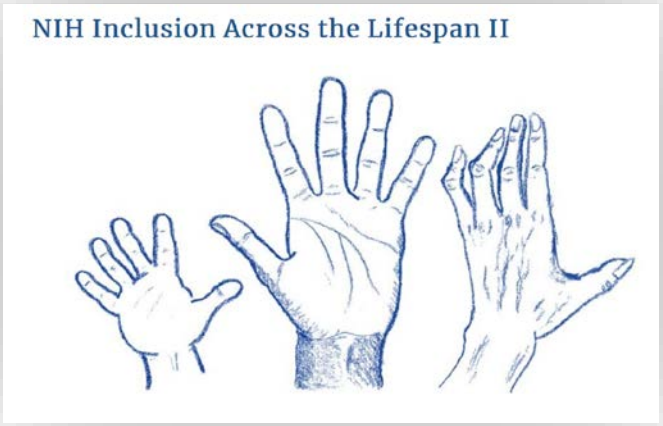
Clinical/Medical

Consider Adoption of NIH Inclusion Across the Lifespan Policy for Industry Trials

- The 21st Century Cures Act directed NIH to collect data on the inclusion of participants in clinical research studies by age
- The *Inclusion Across the Lifespan policy* applies to all NIH competing grant applications on or after 1-25-2019, and requires a plan for including individuals across the lifespan, *and if excluding based on age, provide justification*
- NIH's Scientific Review Groups assess applications
- NIH may seek additional information and determine if the plans need revision and will not fund until concerns are resolved
- Progress reports are required
- https://grants.nih.gov/policy/inclusion/lifespan.htm



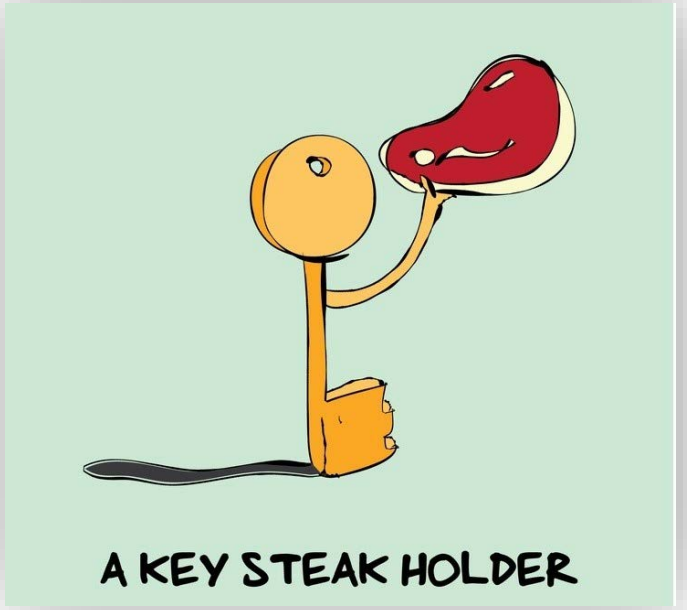
The European Medicines Agency's (EMA) Geriatrics Medicines Strategy

In 2011, the EMA's Committee for Human Medicinal Products adopted the **EMA geriatric medicines strategy**, marking a commitment to improving understanding of how best to evaluate the benefit–risk ratio for a medication in older patients.

"First, the strategy recognizes that older people are the main users of medications — not a minority or special population (a fundamental difference between the geriatric and pediatric populations). Therefore, legislative and regulatory frameworks must be designed to ensure that the use of newly approved medicines in the intended population is supported by relevant data on the benefit–risk balance. The strategy's second aim is to improve the availability of information to patients and prescribers, to support safer use of medications." ***Drug Policy for an Aging Population — The European Medicines Agency's Geriatric Medicines Strategy*** **Francesca Cerreta, Pharm.D., Hans-Georg Eichler, M.D., and Guido Rasi, M.D., N Engl J Med 2012; 367:1972-1974.**

Involve Older Adult Patients from the Beginning of Your Research Study

- Ask an older adult cancer patient to serve on your clinical trial review committee to provide input on your study question, recruitment/retention, study design, and dissemination
- Work with PCORI-funded cancer patient engagement projects to identify people



Thank you!

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