PART 1: STUDY DESIGNS

Overview of the 2020 FDA Draft Guidance for Industry

Inclusion of Older Adults in Cancer Clinical Trials

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Goal of Geriatric Oncology

Improve the **evidence** base for treating older adults with cancer

Improve the **quality of care** received by older adults with cancer

FDA Guidance on Inclusion of Older Adults

1997	Guidance for the Study of Drugs Likely to Be Used in the Elderly
2012	Guidance for Industry: E7 Studies in Support of Special Populations
2019	Enhancing the Diversity of Clinical Trial Populations
2020	**Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or Prior or Concurrent Malignancies (OCE)**
2020	DRAFT Geriatric Labeling Guidance (OND)
2020	DRAFT Inclusion of Older Adults in Cancer Clinical Trials (OCE)

GUIDANCE DOCUMENT

Inclusion of Older Adults in Cancer Clinical Trials

Draft Guidance for Industry

MARCH 2020

Download the Draft Guidance Document | Read the Federal Register Notice

Adequate representation of older adults is necessary to determine benefit-risk of cancer therapeutics in this population

- Early clinical development
  - Enroll older adults in early phase trials, study drug-drug interactions
- **Clinical trials**
  - **Trial design, recruitment strategies, collect additional information, safety monitoring strategies, reporting in discrete age groups**
- Collection of post marketing data through additional trials, registries, and/or real world data

General Recommendations

- Include a representative population including those with frailty

- Strategy for inclusion informed by
  - Prevalence of the condition (breast, lung, colon, DLBCL, MM)
  - Diagnosis and treatment patterns
  - Prior relevant studies
  - Expected differences in safety and efficacy outcomes

Clinical Trials with Registration Intent

Trial Design

- Flexible approaches to trial design
- Consider patient perspectives for trial design including endpoints

Recruitment Strategies

- Consider geography of clinical trial sites
- Format and content of informational material
- Accommodations needed for impairments
- Caregiver support
- Discuss specific goals for enrollment with investigators
- Consider recruiting investigators with expertise in care of older adults with cancer

Clinical Trial Assessments/Reporting

- Collect information on elements from geriatric assessments tools if feasible
- Develop and report more discrete age groups (65-69, 70-74, 75-79, 80+)
- More detailed labeling in Geriatric Use Section (see example below)

8.5 Geriatric Use

Of 284 patients who received PIQRAY in the SOLAR-1 trial, 117 patients were ≥ 65 years of age and 34 patients were ≥ 75 years of age. In patients treated with PIQRAY plus fulvestrant, there was a higher incidence of Grade 3-4 hyperglycemia in patients ≥ 65 years of age (44%) compared to patients < 65 years of age (32%). No overall differences in effectiveness of PIQRAY were observed between patients ≥ 65 years of age compared to younger patients. There are an insufficient number of patients ≥ 75 years of age to assess whether there are differences in safety or effectiveness.

Post Market Considerations

- Ideally, adequate information on older adults should be captured in the premarket clinical trials
- If older adults are not adequately represented, it may be appropriate to develop a plan to collect data on older adults in the postmarket setting.
- **This could be accomplished with post-marketing trials examining a broader population, or through collection of real world data in an observational study or registry.**
- In certain situations, FDA may require postmarket studies and clinical trials.
- Sponsors should prospectively discuss their plan for collecting additional information in the postmarket setting with the CDER or CBER review division or office.
- Postmarket data may provide clinically useful information, that when appropriate, **can be added to the geriatric use section of the labeling.**

PROJECT SILVER

Key Objective: Improving the evidence base for treating older adults with cancer

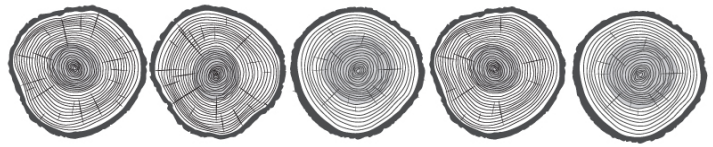
JOURNAL OF CLINICAL ONCOLOGY | ASCO SPECIAL ARTICLE

- Regulatory Policy
- Advocacy and Outreach
- Global Engagement
- Research & Publications

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

See accompanying article doi:10.1200/JCO.2015.62.1854



Opportunities for Systematic Change