May 5, 2020

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Via email: https://www.regulations.gov

Re: Docket No. FDA-2019-D-5572 for “Inclusion of Older Adults in Cancer Clinical Trials, Guidance for Industry.”

On behalf of the Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to cancer patients, survivors, and their loved ones, we appreciate the opportunity to comment on the FDA’s Draft Guidance, Inclusion of Older Adults in Cancer Clinical Trials (“Draft Guidance”). As revealed by the current COVID-19 pandemic, older adults often present with additional needs and considerations that go beyond those of the younger population. It is essential that these unique factors be embraced as informative, rather than disqualifying, in the care older adults receive throughout the entirety of our health care system – including clinical trials. We applaud the FDA for not only acknowledging the importance of including more older adults in clinical trials, but also for recognizing and promoting the need to incorporate the voices, concerns, and preferences of older adults throughout the drug development process. The comments below are provided to highlight and expand upon specific acknowledgements and recommendations set forth in this Draft Guidance.

As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology professionals in the United States, CSC has a unique understanding of the cancer patient experience. Each year, CSC serves more than one million people affected by cancer through its network of over 45 licensed affiliates, more than 170 satellite locations, and a dynamic online community of individuals receiving social support services. Overall, we deliver more than $50 million in free, personalized services each year to individuals and families affected by cancer nationwide and internationally.

Additionally, CSC is home to the Research and Training Institute (RTI)—the only entity of its kind focused solely on the experiences of cancer patients and their loved ones. The RTI has contributed to the evidence base regarding the cancer patient experience through its Cancer Experience Registry (with over 14,000 participants), various publications and peer-reviewed studies on the psychosocial impact of cancer and cancer survivorship. This combination of direct services and research uniquely positions CSC to gather and provide valuable patient feedback.
As the FDA acknowledges, adults aged 65 years and older, and especially those over age 75, are underrepresented in cancer clinical trials. This is true despite age being the greatest risk factor for developing cancer, with approximately 60% of people with cancer being 65 years of age or older (Cancer.net, 2019). Clinical trials provide patients with cancer and other serious medical conditions the opportunity to participate in ground-breaking research that may bring about treatments that improve quality of life, extend survival, and even prove lifesaving. This opportunity should be equally applicable to older adults, including those age 75 and above. CSC shares the commitment, need, and urgency to ensure the broadest and most inclusive patient participation possible in clinical trials while maintaining safety and efficacy standards. Unnecessary barriers and overly restrictive eligibility criteria thwart potential treatment advances, survival increases, and reduction in mortality.

On August 6, 2019, CSC submitted comments in support of the FDA’s draft guidance, Enhancing the Diversity of Clinical Trial Populations – Eligibility Criteria, Enrollment Practices, and Trial Designs (Enhancing the Diversity of Clinical Trial Populations). In those comments, we specifically noted that safety rightfully maintains the top priority in connection with all patients’ participation in clinical trials. As we look to this Draft Guidance and the issue of safety as it specifically pertains to older adults’ participation in clinical trials, CSC supports both of the recommendations set forth in Section A:

- Sponsors should enroll older adults, if appropriate, in early phase studies to obtain information on safety, exposure, and response to better inform the study design.

- Sponsors should evaluate drug-drug interactions early in drug development to allow enrollment of older adults who may otherwise be excluded because of their concomitant medication use.

While increasing older adults’ participation in clinical trials may rightfully begin with the need to address safety and do not harm, it does not end there. As CSC discussed in our August 6, 2019 comments on Enhancing the Diversity of Clinical Trial Populations, and again in our August 26, 2019 comments on the notice New Drugs Regulatory Program Modernization: Improving Approval Package Documentation and Communication, there also exists the obligation to maximize possible benefits and minimize possible harms – an obligation the Belmont Report terms “beneficence” (National Commission, 1979). The background for this Draft Guidance similarly discusses the benefit-risk profile in its recognition that enrolling an adequate representation of the range of patients in a clinical trial that may be exposed to a drug after approval can maximize the generalizability of the trial results. In 2018, CSC joined sixteen other stakeholders endorsing a set of recommendations aimed at reducing barriers to patient enrollment to clinical trials. One of those recommendations addressed eligibility criteria and read, “[e]nsure eligibility criteria do not preferentially exclude a racial or demographic group, e.g. upper age limits, or excluding comorbidities more highly associated with demographic or socioeconomic subgroup unless specific rationale for exclusion exists” (American Cancer Society, 2018).

The recommendations included in Section B of this Draft Guidance speak to many specific examples of beneficence – maximizing possible benefits and minimizing possible harms –
sponsors should consider during drug development for older adults. While CSC supports all of the trial design examples provided in Section B, we particularly applaud FDA’s recommendation that references its June 2018 draft guidance for industry, Patient-Focused Drug Development: Collecting Comprehensive and Representative Input – namely, that sponsors should “[c]onsider perspectives of older adults, including those of patients and patient caregiver partners, clinicians, and advocacy groups, during the design of clinical trial protocols to ensure patient preferences are incorporated in clinical trial activities, when possible, to facilitate enrollment of older adults as well as improve identification of meaningful endpoints and overall trial design.” However, to achieve the Draft Guidance’s expressed goal of developing more information to better inform treatment decisions for older adults with cancer, consideration of older adults’ perspectives must not end with trial design, but instead incorporate all clinical trial activities, including labeling and postmarket analysis.

Consideration and incorporation of older adults’ perspectives speak to Congress’ recognition per the 21st Century Cures Act, as amended by the Food and Drug Reauthorization Act of 2017, on the importance of patient experience data (data collected by any person including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers) that includes the physical and psychosocial impacts of a disease or condition, or related therapy or clinical investigation, on patients’ lives (21st Century Cures Act). Recognizing that patients are the foremost experts in their disease, clinical trial design, trial endpoint selection, regulatory reviews, labeling, and post-market surveillance should all consider and incorporate older adult patients’ experiences, perspectives, needs, and priorities to assist older cancer patients in the future, their loved ones, and their health care team make better informed decisions. Clinical trials that incorporate patient experience data, both physical and psychosocial impacts of the disease or clinical investigation, allow us to better understand a patient’s response to each arm of a trial, as well as meet the patient’s needs and concerns – all goals of 21st Century Cures.

While Section B of the Draft Guidance recommendations state that “[i]ncorporating a patient reported outcome instrument(s) in cancer trials may encourage older adults to participate in clinical trials and the information obtained may inform future research,” PRO’s are limited to a patient reporting the status of his or her health condition and fail to capture the older adult’s full perspective or experience during a clinical trial. In addition, the expressed purpose behind incorporating a PRO instrument – namely to encourage older adults to participate and to inform future research – falls far short of better informing treatment decisions for older adults, and helping future older patients, their loved ones, and their health care team. Similarly, two additional FDA resources mentioned in the background of this Draft Guidance - FDA’s Drug Trials Snapshots and the FDA’s website - provide only demographic information. When recommendations are limited in scope, they miss the opportunity to maximize the possible benefits that could be achieved by the intended population, in this case older adult cancer patients.

When successfully implemented, the Draft Guidance’s recommendations in Section B that encourage sponsors and clinical trial cooperative groups to develop patient recruitment strategies that mitigate challenges specific to older adults are likely to increase enrollment, ensure retention, and enhance the patient experience of older adults. The example of a trial site located
in a more accessible community-based setting as compared to an urban academic setting may ease the travel, cost, and mobility burden imposed on an older cancer patient and his or her caregiver.

In summary, CSC supports the FDA’s Draft Guidance, Inclusion of Older Adults in Cancer Clinical Trials. However, we urge the FDA to encourage sponsors to go beyond the recommendations specifically outlined in the Draft Guidance and to maximize possible benefits for older adults by considering and incorporating their perspectives through patient experience data collected throughout the drug development process. CSC is happy to arrange a time to discuss these comments. Please feel free to contact me at

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References


