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Report on Research Compliance Volume 17, Number 5. April 23, 2020 Draft Guidance to Increase Seniors in Cancer Trials a 'Good First Step'

By Theresa Defino

Study sponsors should be making additional efforts to enroll older individuals in cancer trials, incorporating such strategies in study design and recruitment methods, and as part of postmarket studies. This is because those 65 and older are underrepresented in pre-market research, according to new draft guidance published by the Food and Drug Administration (FDA).[1]

Open for comment until later this month, at least one advocacy group is encouraged by the draft guidance but notes that even more needs to be done, including legislatively. Still, despite being in draft form, the proposed guidance can prove instructive to investigators as they design studies and to institutional review boards as they ponder whether research reflects the intended beneficiaries.

"It's a very good first step," Susan Peschin, president and CEO of Alliance for Aging Research, said of the draft guidance. "It sends a strong message to oncology clinical development programs that they should be deliberate in their recruitment efforts to enlist a group of older adults that reflects the intended population for the treatment being studied and evaluated." The alliance is an advocacy and lobbying group "dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal human experience of aging and health."

The draft guidance isn't FDA's first attempt at promoting the enrollment of older individuals, which it defines as aged 65 and older, with particular concern given to recruiting those over age 75. It was issued by FDA's Oncology Center of Excellence, Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).

FDA: Underenrollment 'Persists'

The first part of the draft guidance makes the case for including the elderly; then it offers some recommendations for doing that.

As FDA notes, cancer "is a disease associated with age, with the number of cancer cases projected to multiply due to rapid aging of the U.S. population," and those in these age groups "are under-represented in cancer clinical trials." This issue, FDA said, "persists" despite the agency's efforts to date.

Having diverse and "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," FDA explained. "It provides the ability to understand the drug's benefit-risk profile across the patient population likely to use the drug in clinical practice (e.g., to identify whether there are differences in the benefits, risks, or both of the drug in different populations). Including information in the labeling describing use in older adults helps to promote the safe and effective use of these products and better informs treatment decisions in clinical practice."

Specifically, younger and older individuals may evidence different responses and toxicity "due to age-related physiologic changes. For example, the pharmacokinetics of the drug, or the pharmacodynamic response to the

drug, or both may vary between younger and older patients," FDA said.

Additionally, "older adults often have comorbidities and may be taking concomitant medications that could impact the efficacy of either the cancer drug or other drug(s) they are taking, and may also impact the incidence and the severity of adverse events," the draft guidance states. "It is important that the spectrum of older adults included in clinical trials are representative of the intended population, including those with physiological decline (e.g., frailty). Furthermore, there may be important differences in efficacy in older patients compared to the younger or general population, and information describing such differences should be conveyed to patients and healthcare providers where appropriate."