

People aged 75 years and older are underrepresented in blood cancer clinical trials

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In the first comprehensive analysis of clinical trial enrollment among older adults with blood cancers, researchers from the U.S. Food and Drug Administration (FDA) found significant gaps in participation among those aged 75 and older when considered against the incidence of these malignancies in this age group, according to research being presented today during the 59th American Society of Hematology (ASH) Annual Meeting and Exposition in Atlanta. By comparison, adults under 65 years tend to be overly represented in these trials, despite the fact that a majority of blood cancers are most frequently diagnosed in those over 65 years of age.

"Until now, there has been very little information about the enrollment of adults with hematologic cancers. Based on our findings, the occurrence of <u>cancer</u> is much higher in adults over 75 years of age compared with the proportion of <u>patients</u> in this age group who enroll in <u>clinical trials</u>," said lead study author Bindu Kanapuru, MD, medical officer in the Division of Hematology Products, Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "With so few patients aged 75 or older enrolled in clinical <u>trials</u>, critical information on the safety and effectiveness of new therapies in this age group is greatly lacking."

The magnitude of the disparity is particularly concerning given that the number of adults aged 75 and older who are diagnosed with <u>blood</u> <u>cancers</u> is only expected to rise as the population ages. Currently, one out of five patients diagnosed with most blood cancers is age 75 and above.

In this study, FDA researchers analyzed data on more than 44,000 patients who were enrolled in clinical trials of <u>drug</u> treatments for blood cancers that were evaluated by FDA as part of the drug approval process between 2005 and 2015.The researchers grouped patients by disease and age (



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