FDA Encourages Inclusion of People With Incurable Cancers in Clinical Trials

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On June 24, the U.S. Food and Drug Administration issued a draft guidance document, "Cancer Clinical Trial Eligibility Criteria: Available Therapy in Non-Curative Settings," which, when finalized, will provide recommendations to sponsors designing clinical trials of drug and biological products to expand eligibility to patients with incurable cancers.

The draft guidance, when finalized, will provide sponsors with recommendations regarding including patients who have not received available therapy/therapies, such as evaluating these patients in separate cohorts from patients who have received available therapies.

"Today, theFDA issued a draft guidance encouraging industry to include patients with incurable cancers (when there is no potential for cure or for prolonged/near normal survival) in cancer clinical trials, regardless of whether they have received existing alternative treatment options. Historically, many clinical trials have required that participating patients previously received multiple therapies," said Richard Pazdur, MD, director of the FDA's Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the FDA's Center for Drug Evaluation and Research.

"The FDA believes patients with incurable cancers, if provided adequate information to make an informed decision, should be eligible to participate in oncology clinical trials. If there is no scientific rationale for excluding these patients, then clinical trial eligibility criteria should be broadened to include these patients, with appropriate informed consent."

"This draft guidance is part of the FDA's broader initiative to encourage rational expanded patient eligibility for oncology clinical trials."

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