# FDA Encourages Inclusion of Incurable Cancers in Trials

On June 24 the U.S. Food and Drug Administration (FDA) issued draft guidance encouraging inclusion of patients with incurable cancers in oncology clinical trials, regardless of prior therapies. "Historically, many clinical trials have required that participating patients previously received multiple therapies," said Richard Pazdur, MD, director of the FDA Oncology Center of Excellence and acting director of the Office of Oncologic Diseases in the 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."

The draft guidance, titled "Cancer clinical trial eligibility criteria: Available therapy in noncurative settings," is part of the FDA's broader initiative to encourage "rational expanded patient eligibility" for oncology clinical trials. When finalized, the guidance will provide recommendations to sponsors designing clinical trials of drug and biologic products for expanding eligibility to patients with incurable cancers as well as inclusion of patients who have not received available therapy/therapies (e.g., evaluating these patients in separate cohorts from patients who have received available therapies). The draft guidance is available at: https://www.federalregister.gov/documents/2021/06/25/2021-13585/cancer-clinical-trial-eligibility-criteria-approach-to-available-therapy-in-non-curative-settings.