FDA Releases Guidance Aimed at Expanding Cancer Trials

Clinical trials often exclude key patient populations, including children and people living with HIV or hepatitis B or C.

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As part of an effort to expand clinical trial eligibility, the Food and Drug Administration (FDA) released five guidance documents last week recommending ways cancer researchers could expand their trials to include several key patient populations—including children, people living with HIV or viral hepatitis, those with heart, kidney or liver problems, and those with other cancers, Endpoints News reports.

Published last Tuesday, the five draft guidance documents address cancer clinical trial eligibility criteria and the inclusion of adolescent patients in adult oncology trials.

One guidance document explains how clinical trials seeking to include children in adult cancer trials should evaluate pediatric formulations, noting evidence that supports the inclusion of young patients between 2 and 12 years old. Another recommends that both pediatric and adolescent patients be included in early-phase clinical trials—as long as adult safety and toxicity data have been obtained first.

Another guidance document recommends expanding cancer clinical trial eligibility to some people living with HIV, hepatitis B virus or hepatitis C virus. That guidance argues that doing so may help accelerate the development of effective therapies in cancer patients with chronic conditions, potentially making thousands of such patients eligible to participate in clinical trials.

Other documents include new guidance on how to include people with kidney dysfunction, cardiac conditions and non-hepatitis liver disease as well as patients with previous or concurrent types of cancer. A final report recommends that people with brain metastases be included in clinical trials in order for researchers to better understand the efficacy and safety profiles of investigational drugs.

“Overly restrictive eligibility criteria may slow patient accrual, limit patients’ access to clinical trials and lead to trial results that don’t fully represent treatment effects in the patient population that will ultimately receive the drug,” said former FDA Commissioner Scott Gottlieb, who resigned from his post last week.

To learn more about cancer clinical trial eligibility, click here.

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