FDA Guidance Provides New Details on Diversity Action Plans Required for Certain Clinical Studies

Enhancing diversity in clinical studies facilitates broader applicability of results across a broad spectrum of patient populations.

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[On June 26], the U.S. Food and Drug Administration issued a draft guidance, "Diversity Action Plans to Improve Enrollment of Participants from Underrepresented Populations in Clinical Studies," to assist medical product sponsors in submitting Diversity Action Plans to support certain clinical studies. Diversity Action Plans are intended to increase clinical study enrollment of participants of historically underrepresented populations to help improve the data the agency receives about the patients who may potentially use the medical product.

Enhancing diversity within clinical studies not only facilitates broader applicability of results across a broad spectrum of patient populations, but also enhances understanding of the disease or medical product under study, thus providing valuable insights to inform the safe and effective use of the medical product among patients.

"Participants in clinical trials should be representative of the patients who will use the medical products," said FDA Commissioner Robert M. Califf, MD. "The agency's draft guidance is an important step—and one of many ongoing efforts—to address the participation of underrepresented populations in clinical trials to help improve the data we have about patients who will use the medical products if approved."

This draft guidance describes the format and content of Diversity Action Plans, the medical products and clinical studies for which a Diversity Action Plan is required, as well as the timing and process for submitting Diversity Action Plans to the FDA. The draft guidance also outlines the criteria and process the agency will use to evaluate a sponsor's request not to submit a required Diversity Action Plan, also known as a waiver.

Diversity Action Plans must specify the sponsor's rationale and goals for clinical study enrollment (separated by the age group, ethnicity, sex and race of clinically relevant study populations) and describe how the sponsor intends to meet those goals. The guidance also urges sponsors and investigators to consider the many dimensions of clinical trial diversity, even those that extend

beyond age, ethnicity, sex, and race to enroll populations that represent the patients who will be treated if the product is approved.

The requirement for sponsors to submit Diversity Action Plans comes from new provisions of the Federal Food, Drug and Cosmetic Act added by the Food and Drug Omnibus Reform Act (FDORA). These plans apply to phase 3 clinical studies or, as appropriate, other pivotal clinical studies of a drug or biological product, as well as for certain clinical studies of devices, including those intended to serve as the primary basis for the FDA's evaluation of the safety and effectiveness and benefit-risk determination of the device. The requirement to submit a Diversity Action Plan applies to clinical studies for which enrollment begins 180 days after publication of the final guidance.

"Generating data for a broader and more representative population early in the clinical development program is among the FDA's priorities to bring innovative medical products to the public. With FDORA, there is now a requirement for sponsors to submit diversity action plans. These plans may help ensure that sponsors are thinking critically and intentionally about the many characteristics of the patient population they aim to treat when designing their clinical study," 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 draft guidance was developed by the Oncology Center of Excellence Project Equity in collaboration with the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Office of Women's Health, and the Office of Minority Health and Health Equity.

Comments on the draft guidance should be submitted within 90 days after publication in the Federal Register to Regulations.gov. All written comments should be identified with the docket number and with the title of the guidance document.

This news release was published by the Food and Drug Administration on June 26, 2024.
