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FDA Plan Strives to Increase Diversity in Research, Build Trust

By Nina Youngstrom

The Food and Drug Administration (FDA) has put out draft guidance to light a fire under the industry to diversify its research enrollment. In keeping with the Biden administration's push for health equity, the FDA is encouraging more enrollment in clinical trials of research subjects who aren't only white people (mostly men) with higher incomes, which historically has been the norm, experts say.

The April draft guidance encourages clinical-trial sponsors to have a diversity plan that's designed to increase enrollment in research of "underrepresented racial and ethnic populations in the U.S.," the FDA said.[1] "That's exciting and helpful and it fits together with the health outcomes related to COVID-19," said Deborah Biggs, a principal at PYA.

There have been "disparities in how people fared with COVID," added attorney Genevieve deLemos, former research compliance officer at Atrium Health in Charlotte, North Carolina, who is now with deLemos & Wever PLLC. They mirror the lack of diversity in research, which is nothing new. "The health disparities highlighted the need for improved research participation across broader populations, a long-recognized issue that the pandemic put at the forefront of many health care leaders. Action is now being taken to address this historical fault in clinical research through guidance such as this," deLemos said.

According to the FDA draft guidance, "The purpose of this guidance is to provide recommendations to sponsors developing medical products on the approach for developing a Race and Ethnicity Diversity Plan (henceforth referred to as the 'Plan') to enroll representative numbers of participants from underrepresented racial and ethnic populations in the United States, such as Black or African American, Hispanic/Latino, Indigenous and Native American, Asian, Native Hawaiian and Other Pacific Islanders, and other persons of color, in clinical trials."[2] For example, "The Plan should outline the sponsor's plan to collect data to explore the potential for differences in safety and/or effectiveness associated with race and ethnicity throughout the entire development life-cycle of the medical product and not just during the pivotal trial(s) or studies."