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The FDA pulls key DEI initiative for cancer studies from its website

JANUARY 25, 2025 · 11:35 AM ET

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Key guidance to industry on enhancing diversity in clinical trials of cancer drugs disappeared from the Food and Drug Administration website.
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The Food and Drug Administration has removed webpages about diversity and inclusion in clinical trials for cancer drugs.

The page for Project Equity, a 2021 initiative launched by the FDA's Oncology Center of Excellence to ensure that cancer drugs were evaluated for approval based on data from a diverse group of study participants, has gone dark.

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The program aimed to develop policies to make clinical trials for treatments more accessible to people who had been underrepresented in this research in the past. The removal comes amid the Trump administration's push to terminate diversity, equity,

inclusion, and accessibility programs and initiatives.

According to archived Project Equity pages, historically underrepresented groups included "racial and ethnic minorities, individuals who live in rural areas, sexual and gender minorities, and individuals with economic, linguistic, or cultural barriers to healthcare services."

Project Equity wasn't the first time the agency sought to address inclusivity problems in clinical trials, but it helped lead to the development of formal guidance around "diversity action plans." That gave the FDA a way to communicate expectations to drugmakers about how clinical trials should be conducted to support a drug approval.

Several guidance documents were offline early this week, but at least one of them has since been restored.

There is a formal process for removing guidance documents, which are also posted in the *Federal Register*. That seems to have been ignored in this case.

Many in the scientific community have said they will continue their clinical trial inclusion efforts no matter what, says Dr. Lindsay McNair, a clinical research consultant and a research ethicist at Equipoise Consulting.

"This wasn't just kind of an effort to be woke," says McNair. "This wasn't just diversity for the sake of political correctness. This is diversity because it's necessary for scientific reasons."

Studies of new therapies can't tell scientists how they'll work in the real world, if the study population looks nothing like the people who will be treated with the drugs once they're approved, she says. Clinical trials are designed to show scientists, doctors and regulators whether new drugs work and what kinds of side effects they carry.

In response to NPR questions about the removal of Project Equity information, the FDA sent the following email: "HHS has issued a pause on mass communications and public appearances that are not directly related to emergencies or critical to preserving health. This is a short pause to allow the new team to set up a process for review and prioritization. There are exceptions for announcements that HHS divisions believe are mission critical, but they will be made on a case-by-case basis."

"It's hard for me to understand why anyone would be opposed to clinical trials including the variety of people for whom the drug or device is intended," Dr. Robert Califf, the most recent FDA commissioner in the Biden administration, told NPR. "That's the essence of the FDA guidances."

Califf says that nothing really gets "deleted" from the internet, and people who want to find information about trial inclusivity will be able to find it. "But I think if you make information hard to get, and especially if you punish people for doing things by the old information, that's serious."

FDA efforts to improve clinical trial equity and inclusion went beyond race and sex, he says. A big part of the initiative was to get more people involved in clinical trials from rural parts of the country, for example.

"Let's say you have cancer and you need to go into a cancer clinical trial," he says. "You know, a lot of people don't live anywhere near a cancer center. So how are they going to get there?"

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