



Minorities in Clinical Trials



Why do we need minorities in clinical trials?

In clinical trials, research participants should represent the patients who will use the medical product. This is important to address health disparities—diseases that may occur more frequently, or have a different course of disease in certain populations. However, clinical trials often don't reflect real-world patients—racial and ethnic minorities are underrepresented in clinical research.

Why is this important? Men and women of varied races, ethnicities, and ages may have different reactions to a medical product (for example, a medicine, medical device, or vaccine). We are committed to working with companies to improve diversity in clinical trials. That's why we launched the Drug Trials Snapshots in 2015—the snapshots are a database of recent drug approvals that increase transparency about clinical trials participation.

Drug Trials Snapshots show you who participated in the clinical trial for a new medicine.

www.FDA.gov/DrugTrialsSnapshot

What do you need to know about clinical trials?

At FDA, we encourage diverse people like you to participate in a clinical trial so that the agency is better able to determine the safety and efficacy of the product being tested. Here are three things you should know:

- **Clinical trials are voluntary research studies conducted in people**—they are designed to answer specific research questions about medical products like medicines and devices. Researchers must follow strict safety guidelines when medical products are tested in humans to make them as safe as possible. Additionally, medical products tested in humans have already gone through several rounds of testing in the laboratory and in animal studies.
- If you decide to join a clinical trial, **you have can quit at any time with no consequences.**
- **FDA does not conduct clinical trials.** However, we work with companies who develop medical products to ensure that their clinical trials provide enough information for FDA to determine if the products are safe and effective for the patients likely to need them.

2016: The Year of Clinical Trials Diversity

FDA is making a strong push to improve minority participation in clinical trials—this is the "year of clinical trial diversity."

FDA was congressionally mandated to address clinical trial diversity in the Food and Drug Safety and Innovation Act (FDASIA)—Section 907.

FDA investigated medical products submitted to FDA for approval to determine 1) how well demographic subgroups (sex, age, race, and ethnicity) were represented in clinical trials for those medical products, and 2) if there is enough data on demographic subgroups to determine if the medical product is safe and effective for everyone.

Action on FDASIA 907 is organized around 27 action items laid out in the **2014 Action Plan to Enhance the Collection and Availability of Demographic Subgroup Data**. This initiative is led by the FDA Office of Minority Health and supported by various FDA Centers and Offices. It targets demographic subgroups in clinical trials and aims to:

1. **Improve quality and quantity of data derived from underrepresented groups in clinical trials;**
2. **Increase their participation in clinical trials; and**
3. **Make data from clinical trials publically available.**

Why participate in clinical trials?

- Clinical trials are the safest way to try a new medical product if the standard course of treatment does not work for you.
- You can contribute to the greater good. Your participation ensures that a new medical product's benefits and risks are studied in a diverse population.
- You can help researchers find better ways to fight diseases.

It is important to remember that healthy volunteers can also participate in clinical trials.



If you think a clinical trial may be right for you, talk to your doctor. You can also search for clinical trials on www.ClinicalTrials.gov.

ClinicalTrials.gov is an online database of clinical trials sponsored by FDA and the National Institutes of Health (NIH).