



Plans and Enrollment Often Fell Short for Underrepresented Groups in a Sample of NIH-Funded Clinical Trials

Why OIG Did This Review

- Underrepresented racial groups, ethnic groups, and females are disproportionately burdened by many diseases yet have historically been underrepresented in medical research.
- This underrepresentation can exacerbate preexisting health disparities.
- A recent National Academies of Science report highlighted the increasingly diverse U.S. population while emphasizing the urgency of improving diverse representation in clinical research to combat health disparities.

What OIG Found

Researchers in our sample often fell short in enrolling underrepresented groups in NIH-funded clinical trials and in meeting NIH's requirements for inclusion enrollment plans.

- Two-thirds of the clinical trials in our sample had inclusive enrollment plans, but one-third did not plan to include all racial and ethnic groups.
- Slightly more than half of clinical trials in our sample were missing required information that would explain the planned target population.
- Most completed clinical trials in our sample missed planned enrollment targets for underrepresented groups.
- NIH monitors clinical trial enrollment but has had limited success spurring improvement.

What OIG Recommends

OIG recommends that NIH:

1. Hold researchers accountable for clearly describing the rationale for planned study population, as required by NIH policy.
2. Develop additional ways of supporting researchers in meeting inclusion enrollment targets.
3. Promptly take steps to align NIH's demographic data collection and reporting with the revised OMB requirements and obtain more precise clinical trial inclusion enrollment data.

NIH concurred with all three recommendations.