



Diversifying Clinical Trials

WHY IT MATTERS

Including women and historically excluded groups in clinical research has long been viewed as a worthy goal. What are the consequences of not meeting this goal?



1

Generalizability of Research Findings Is Compromised

Women, pregnant people, children, older adults, and racial and ethnic minorities can have distinct health circumstances that affect how they will respond to a drug or therapy. Such differences contribute to variable therapeutic responses and necessitate targeted efficacy and safety evaluation.

2

Hundreds of Billions of Dollars Is Lost

For example, health disparities in diabetes will cost society more than \$5 trillion through 2050—including mortality, morbidity, and loss of work. Disparities in heart disease would cost more than \$6 trillion, and hypertension even more.

3

Innovation Is Hindered

A lack of diversity in study participants hinders exploration of variation in the overall effectiveness of a particular intervention. It also inhibits the identification of new biological processes that could lead to new discoveries important for all populations.

4

Low Accrual Is Compounded

Low accrual, or the number of people in a study, is the number one problem that causes clinical trials to fail. Increasing enrollment of underrepresented populations would help solve this problem, thereby reducing inefficiency and waste, while also helping to ensure clinical data is more representative of the whole population.

5

Lack of Access to Effective Medical Interventions

Clinical trials are a significant, and sometimes the only, point of access for the most cutting-edge therapies for advanced disease. Lack of inclusion in clinical trials for advanced therapeutics may result in lack of access to these life-saving interventions.

6

Trust Is Undermined

Distrust of the clinical research enterprise and medical establishment rooted in historical and contemporary abuse has been documented as a barrier to participation in clinical studies among some populations.

7

Health Disparities Are Compounded

Achieving health equity and reducing health disparities requires far more than just equitable representation in clinical research, and failure to achieve equity on this dimension leaves health disparities unaddressed and reinforces inequities.



READ THE FULL REPORT

www.nationalacademies.org/improve-representation

Copyright 2022 by the National Academy of Sciences. All rights reserved.

The National Academies of
SCIENCES • ENGINEERING • MEDICINE