NATIONAL ACADEMIES Sciences Engineering Medicine

Improving Representation in Clinical Trials and Research

Building Research Equity for Women and Underrepresented Groups

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The case for representation & inclusion in clinical trials & clinical research

Why Diverse Representation in Clinical Research Matters

1. Lack of representation compromises generalizability of clinical research findings to the U.S. population.
2. Lack of representation may hinder innovation.
3. Lack of representation may compound low accrual that causes many trials to fail.
4. Lack of representation may lead to lack of access to effective medical interventions.
5. Lack of representation may undermine trust.
6. Lack of representation compounds health disparities in the populations currently underrepresented in clinical trials and clinical research
7. Lack of representation may cost hundreds of billions of dollars

DIABETES

Nearly 1 Year

Increase in life expectancy

1+ Year

Increase in disability-free life years

1/2 Year

Increase in years in the workforce

HEART DISEASE

1+ Year

Increase in life expectancy

1.5 Years

Increase in disability-free life years

1/3 Year

Increase in years in the workforce

HYPERTENSION

Nearly 1 Year

Increase in life expectancy

1.5 Years

Increase in disability-free life years

3/10 Year

Increase in years in the workforce

Economic Cost of Health Disparities

If all life expectancy disparities were eliminated for the 3 conditions, the value is approximately

$19.5 trillion

Value for even a modest reduction in health disparities due to better representation in clinical trials would be worth **billions of dollars.**

For example, if 1% of health disparities were alleviated by better representation in clinical research, it would result in more than **$40 billion** in gains for diabetes and **$60 billion** for heart disease alone.

The case for representation & inclusion in clinical trials & clinical research

Current status

Current Status of Clinical Trial Participation in the United States

	2013 (%)	2014 (%)	2016 (%)	2017 (%)	2018 (%)
Female	44.3	47.2	54.1	47.9	52.4
American Indian	2.1	1.3	0.8	0.7	1.0
Asian	15.1	17.2	8.4	26.4	7.8
Black/African American	12.2	14.3	10.0	10.8	13.5
Native Hawaiian/Pacific Islander	0.3	0.3	0.6	0.1	0.2
White	52.9	49.5	49.6	49.9	60.0
More than 1 race	1.1	1.1	2.0	1.9	2.3
Unknown race	1.1	1.1	2.0	1.9	2.3
Hispanic	9.8	8.1	10.8	6.7	8.5
Non-Hispanic	86.1	89.6	62.6	81.8	76.2
Unknown ethnicity	4.1	2.3	22.4	9.8	12.0
Sum of all races	84.7	84.8	73.5%	91.8	87.2
Sum of all ethnicities	100.0	100.0	95.8	98.3	96.7

- Data reporting practices are insufficient
- Women now represent over 50 percent of clinical trial participants in the U.S.
- Pregnant and lactating people, SGM populations, and racial and ethnic subgroups of women remain underrepresented
- Racial and ethnic diversity of clinical trials in largely stagnant

01

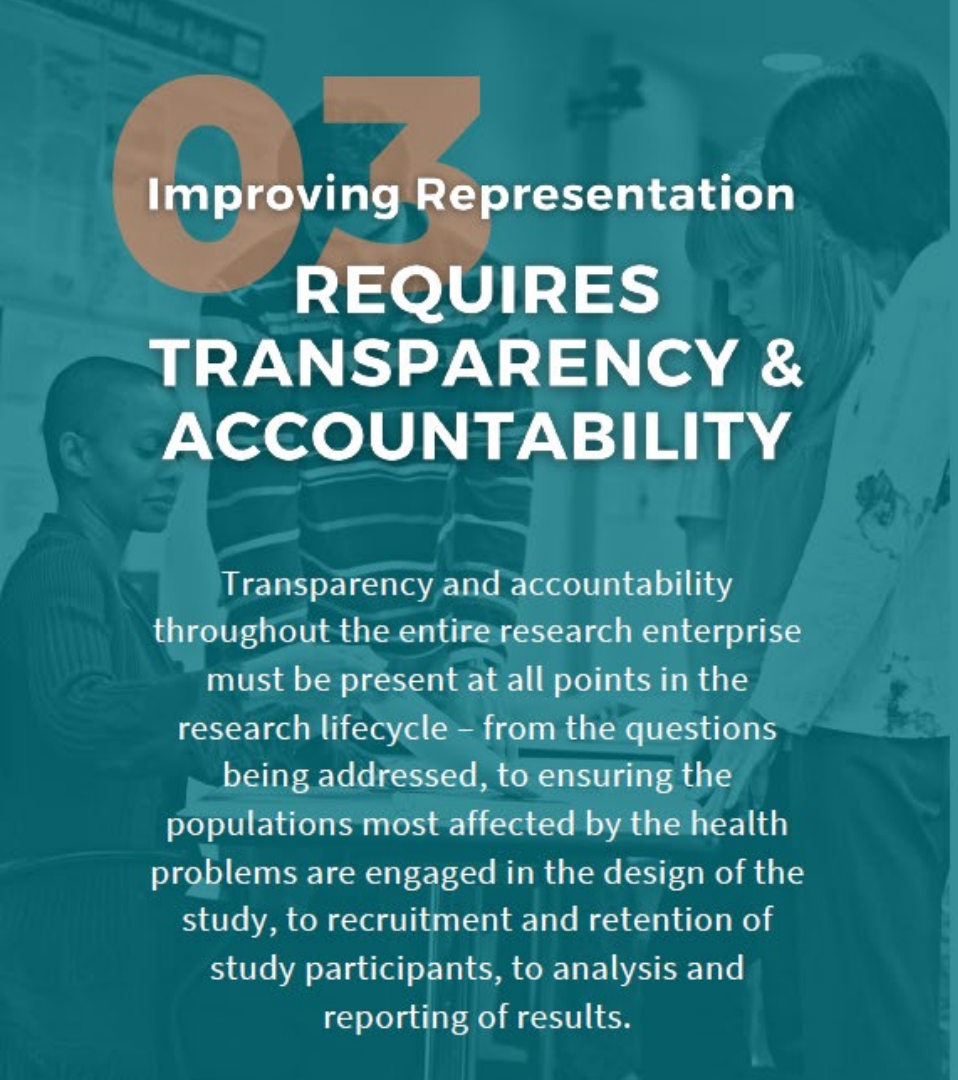
Improving Representation IS URGENT

Despite greater diversity in the United States today, deep disparities in health are persistent, pervasive, and costly. Failing to reach these growing communities will only prove more costly over time and prevent meaningful reductions in disparities in chronic diseases.

02

Improving Representation REQUIRES INVESTMENT

In order to better address health disparities, our workforce should look more like our nation. Building trust with local communities cannot be episodic or transactional and pursued only to meet the goals of specific studies; it requires sustained presence, commitment, and investment.



03

Improving Representation

REQUIRES TRANSPARENCY & ACCOUNTABILITY

Transparency and accountability throughout the entire research enterprise must be present at all points in the research lifecycle – from the questions being addressed, to ensuring the populations most affected by the health problems are engaged in the design of the study, to recruitment and retention of study participants, to analysis and reporting of results.

04

Improving Representation

IS THE RESPONSIBILITY OF EVERYONE INVOLVED

The clinical research landscape involves multiple stakeholders— participants, communities, investigators, IRBs, industry sponsors, institutions, funders, regulators, journals, and policy-makers. The responsibility (and cost) will be borne to some extent by all stakeholders in the larger research ecosystem, acting in consort to improve representation.

05

CREATING A MORE EQUITABLE FUTURE ENTAILS A PARADIGM SHIFT

The clinical research field must embrace a paradigm shift that moves the balance of power from institutions and puts at the center the priorities, interests, and voices of the community.

An ideal clinical trial and research enterprise pursues justice in the science of inclusion through scalable frameworks, expects transparency and accountability, invests more in people, institutions and communities to drive equity, and invests in the science of community engagement and empowerment.

The case for representation & inclusion in clinical trials & clinical research

Current status – including facilitators & barriers

Recommendations

Recommendations
Reporting

- **The Department of Health and Human Services (HHS) should establish an intradepartmental task force on research equity charged with coordinating data collection and developing better accrual tracking systems across federal agencies**

- **The NIH should standardize the submission of demographic characteristics for trials to ClinicalTrials.gov beyond existing guidelines so that trial characteristics are labeled uniformly across the database and can be easily disaggregated, exported, and analyzed by the public**

- **Journal editors, publishers, and the International Committee on Medical Journal Editors should require information on the representativeness of trials and studies for submissions to their journals**

Recommendations
Accountability

- **The Food and Drug Administration should require study sponsors to submit a detailed recruitment plan no later than at the time of Investigational New Drug and Investigational Device Exemption application submission that explains how they will ensure that the trial population appropriately reflects the demographics of the disease or condition under study**
- **In grant proposal review, the NIH should formally incorporate considerations of participant representativeness in the score-driving criteria that assess the scientific integrity and overall impact of a grant proposal.**
- **The Office of Human Research Protections (OHRP) and the FDA should direct local institutional review boards (IRBs) to assess and report the representativeness of clinical trials as one measure of sound research design that it requires for the protection of human subjects.**
- **The CMS should amend its guidance for coverage with evidence development to require that study protocols include a plan for recruiting and retaining participants who are representative of the affected beneficiary population and a plan for monitoring achievement of representativeness and a process for remediation if CED studies are not meeting goals for representativeness.**

Recommendations
Federal Incentives

- **Congress should direct the FDA to enforce existing accountability measures, as well as establish a taskforce to study new incentives for new drug and device for trials that achieve representative enrollment.**
- **The CMS should expedite coverage decisions for drugs and devices that have been approved based on clinical development programs that are representative of the populations most affected by the treatable condition.**
- **CMS should incentivize community providers to enroll and retain participants in clinical trials by reimbursing for the time and infrastructure that is required.**
- **The Government Accountability Office (GAO) should assess the impact of reimbursing routine care costs associated with clinical trial participation for both Medicare (enacted in 2000) and Medicaid (enacted in 2020).**

Recommendations
Remuneration

- **Federal regulatory agencies, including OHRP, NIH, and FDA, should develop explicit guidance to direct local IRBs on equitable compensation to research participants and their caregivers.**

- **All sponsors of clinical trials and clinical research (e.g., federal, foundation, private and/or industry) should ensure that trials provide adequate compensation for research participants.**

Recommendations
Education, Workforce, and Partnerships

- **All entities involved in the conduct of clinical trials and clinical research should ensure a diverse and inclusive workforce, especially in leadership positions.**
- **Leaders and faculty of academic medical centers and large health systems should recognize research and professional efforts to advance community-engaged scholarship and other research to enhance the representativeness of clinical trials as areas of excellence for promotion or tenure.**
- **Leaders of academic medical centers and large health systems should provide training in community engagement and in principles of diversity, equity, and inclusion for all study investigators, research grants administration, and IRB staff as a part of the required training for any persons engaging in research involving human subjects.**
- **HHS should substantially invest in community research infrastructure that will improve representation in clinical trials and clinical research.**

Thank you!