Improving Representation in Clinical Trials and Research

Building Research Equity for Women and Underrepresented Groups

The National Academies of Sciences, Engineering, and Medicine undertook the most comprehensive examination to date of the representation of women and underrepresented populations in clinical trials in research. This included a review of the health and economic impact this lack of inclusion has on the United States, a review of factors that prevent full inclusion, and facilitators to broaden representation in clinical trials and research in the United States.

The study committee found that while progress has been made with representation of white women in clinical trials and clinical research, there has been little progress in the last three decades to increase participation of racial and ethnic minority population groups. This underrepresentation is compounding health disparities, with serious consequences for underrepresented groups and for the nation.

A common trope is that communities underrepresented in trials are not willing to participate in research. However, the evidence is clear that American Indian or Alaska Native, Asian, Black, and Hispanic individuals are no less likely, and in some cases are more likely, to participate in research when asked. Although mistrust and distrust exist within certain communities, the research shows that this is a surmountable barrier when research is done respectfully and in partnership with communities.

The report emphasizes the urgency needed to address lack of equitable participation in clinical trials, as failure to do so will only prove more costly over time and will prevent meaningful reductions in disparities in chronic conditions. However, improving representation in clinical trials and research requires an investment of time, money, and effort. Building trust with local communities requires a sustained commitment and presence and investing in systems and technologies to reduce barriers to participation takes resources. This investment is the responsibility of everyone involved in the clinical research landscape, which is complex and involves multiple stakeholders. However, we must *all* make this a priority to drive change on a systems level.

Industry sponsors have a major role to play, as the majority of clinical trials in the United States are sponsored by industry. The priorities of research sponsors heavily influence the research that is done and the questions that are asked, and therefore present an opportunity to drive change on a meaningful level with appropriate incentives and accountability measures for diversifying trials.

The committee approached its recommendations by thinking about systems-wide changes. Although there are many things that individual investigators in industry can do to more successfully recruit and retain diverse study participants in trials that are outlined in Chapter 5 of the report, the committee focused on system-level recommendations to drive change on a broader scale. The committee acknowledges that changing our nation's approach to clinical research may require significant upfront costs to more equitably recruit and retain a diverse group of participants and to hold investigators accountable when they do not meet these goals. It will also require incentivizing sponsors of clinical research to change the status quo.

Below are a set of recommendations that provide incentives for industry to diversify trials, along with some recommendations to hold industry sponsors accountable for ensuring that the individuals enrolled in their trials reflect the US population. There are also recommendations directed at industry to consider the diversity of their workforce and investigators, as well as compensating their research participants equitably.

RECOMMENDATION 2

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.

RECOMMENDATION 7

The CMS should amend its guidance for coverage with evidence development to require that study protocols include a plan for recruiting and retaining participants that are representative of the affected beneficiary population and a plan for monitoring achievement of representativeness, including a process for remediation if CED studies are not meeting these goals.

RECOMMENDATION 8

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.

RECOMMENDATION 9

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.

RECOMMENDATION 13

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.

RECOMMENDATION 14

All entities involved in the conduct of clinical trials and clinical research should ensure a diverse and inclusive workforce, especially in leadership positions.

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For additional information regarding the consensus study, visit http://www.nationalacademies.org/cwsem.

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