Reducing diversity gaps in clinical trials is a societal imperative, according to report

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"The recommendations outlined in my paper provide a road map for achieving inclusiveness, ensuring the validity of clinical research, enhancing health equity and improving health outcomes for all," says Jonathan Watanabe, UC Irvine professor of clinical pharmacy practice and director of the campus's Center for Data-Driven Drugs Research and Policy. Credit: Steve Zylius / UC Irvine

From costing society an estimated $11 trillion to hindering new discoveries in medicine and preventing access to effective interventions, underrepresentation of women, older adults and minorities in clinical research has several significant consequences, according to recent analyses commissioned by the National Academies of Sciences, Engineering and Medicine.

Jonathan Watanabe, UC Irvine professor of clinical pharmacy practice and director of the campus's Center for Data-Driven Drugs Research and Policy, recently provided expert commentary on the issue published online in the *Journal of the American Geriatrics Society*.

He provides recommendations and cites progress achieved based on NASEM activities between 2020 and 2022 that examined and identified the challenges and opportunities involved in overcoming barriers to increased research participation by diverse populations.

Women are more likely to experience dementia, and older adults are particularly affected by chronic conditions like diabetes, heart disease and hypertension, requiring multiple medications, yet they're marginalized in clinical trials. Addressing this is crucial for advancing health equity and elevating the quality of care for these excluded groups.

"The goal of my paper is to empower efforts on multiple levels to enhance the representation of women, minorities and older adults to improve their health outcomes. It serves as a valuable resource of actionable suggestions and reports on the progress that's been made through coordinated national policy efforts and collaboration from various stakeholders, including research institutions, funding bodies and medical journals," Watanabe says.

Importantly, numerous mandated policies have now been issued to boost representation, and federal regulations now require trial sponsors to

submit diversity action plans when presenting study protocols. Enrollment goals and their rationale, as well as strategies for achieving them, must be included, along with details on age group, sex, racial and ethnic characteristics, disease prevalence among different demographics, specific outreach and enrollment methods, inclusion criteria, and diversity training for study personnel.

Enhancing the diversity of the workforce is also critical for health equity. It has repeatedly been shown that inclusivity in this group improves the ability to understand sectors of the population that are still regularly absent from clinical research on conditions that affect them and leads to increased representation in clinical studies.

"Addressing study participant and workforce inclusion gaps is both achievable and necessary. It requires intentional and committed efforts now coordinated by a broad range of stakeholders," Watanabe says.

"Fortunately, thanks to NASEM and the resulting federal efforts, we have taken a crucial step forward in improving the quality and applicability of clinical studies and now have informed guidance that can be applied to ensuring equitable representation and improving health outcomes for all."

More information: Jonathan H. Watanabe, Enhancing drug evaluation in diverse populations and older adults: National Academies of Sciences, Engineering, and Medicine considerations, *Journal of the American Geriatrics Society* (2024). DOI: 10.1111/jgs.19075

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