

## Clinical trial leadership still includes disproportionately low number of women

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Women remain underrepresented in leading cardiovascular clinical trials, which corresponds with underrepresentation and a lack of gender diversity among presenters at scientific meetings, according to a review published today in the *Journal of the American College of Cardiology*.

A previous analysis of cardiovascular trials published over the last four years found that women comprised only 10.1% of clinical trial leadership committees, and more than half of the trials had no women as part of the trial leadership team. Other research has also found a correlation between women leading clinical trials and the number of women participating in clinical trials. Historically, clinical trials have largely enrolled white men, and participation has been low among women, older adults and racial/ethnic minorities. The current review highlights gender diversity of panelists and session chairs at the recent ACC Scientific Sessions, but demonstrates that 93% of the clinical trial results were presented by men.

"These problems are, unfortunately, cyclical in

nature. A lack of women in leadership positions on clinical trials results in fewer women participating in the trials. The fewer women participating in studies means that medications and other therapies aren't ensured to be safe and effective for everyone," said Mary Norine Walsh, MD, MACC, medical director of the heart failure and cardiac transplantation programs and the Cardiovascular Research Institute at Ascension St. Vincent Heart Center in Indianapolis, and author of the paper. "Fewer women leading clinical trials also means fewer women presenting pivotal, practice-changing trial results at scientific meetings."

Walsh said that increasing the number of women on trial steering committees needs to start at a deeper level. Mentorship in early career is crucial as is knowledge of clinical trial committee structure. To help ensure this, medical societies have begun to release recommendations and roadmaps to foster change, including the ACC's "Clinical Trial Research: Upping Your Game" program, designed to help develop and train the next generation of women and underrepresented minorities as clinical trialists.

"We're starting to see work being done to close the gap in representation, but more needs to be done," Walsh said. "Scientific sessions and meeting planners only have so much influence over who is presenting at conferences. This comes down to senior clinical trialists relinquishing the podium and giving a leg up to others."

Walsh laid out steps to increase representation in clinical trial leadership, including:

- Federal and industry sponsors of clinical trials need to insist on diversity of the trial steering committee.
- Investigators asked to lead clinical trials must consider geographic, institutional and trial site diversity, along with a diverse slate of experienced investigators in leadership



## positions.

- Institutions, department chairs and division chiefs need to encourage women to serve as site principal investigators.
- The informal or formal pecking order of cardiovascular trial leadership needs to be reworked.
- Women should not be tapped for clinical trial leadership and late-breaking results reporting only if the trial is pertinent solely to a female patient population.

"There will be no room at the top for new and innovative investigators to shine if those who have already achieved success don't make room," Walsh said.

For more information on increasing diversity in clinical trial participants, check out <a href="https://www.CardioSmart.org/clinicaltrials">www.CardioSmart.org/clinicaltrials</a>.

**More information:** Mary N. Walsh, Gender Diversity in Cardiovascular Clinical Trial Research Begins at the Top, *Journal of the American College of Cardiology* (2022). DOI: 10.1016/j.jacc.2022.01.001

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