Diversifying Clinical Trials: A Path Forward

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Equity <1% in:	Applied Therapeutics, Elixir Medical, Stel, ControlRad (spouse);
No Fees from:	AMA (Scientific Advisory Board), SCAI (Women in Innovations Committee Member); Faculty CRF;
Honorarium:	JAMA Cardiology (Associate Editor), ACC (BOT Member, SC Member CTR Program)

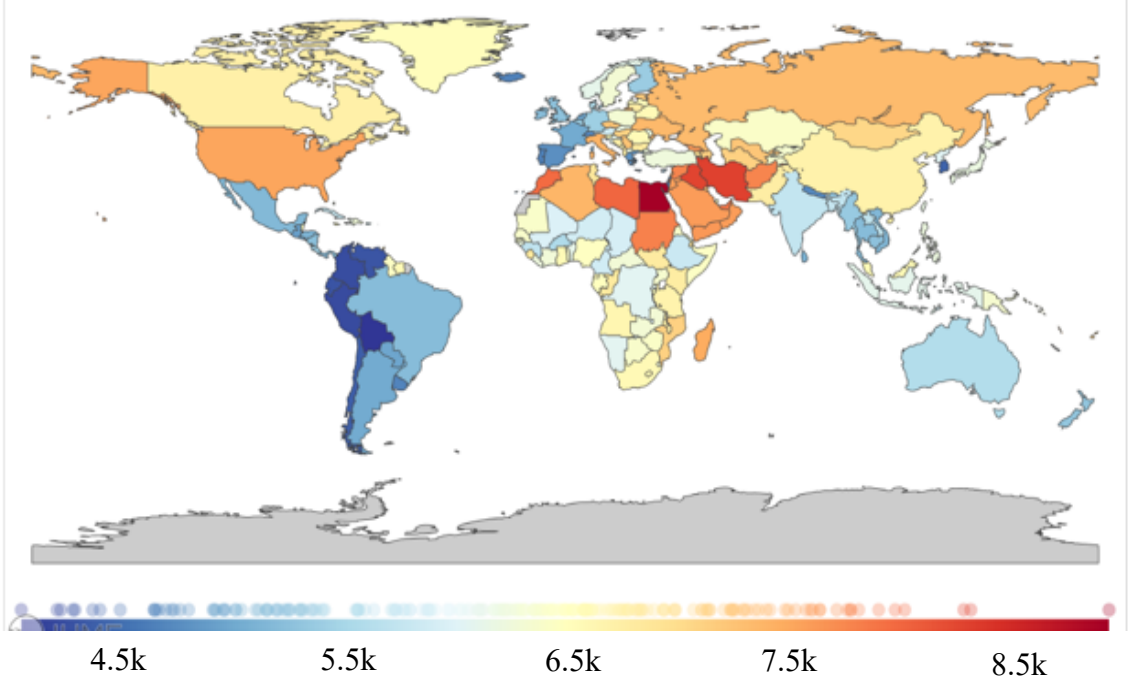
Gender disparities in CV health

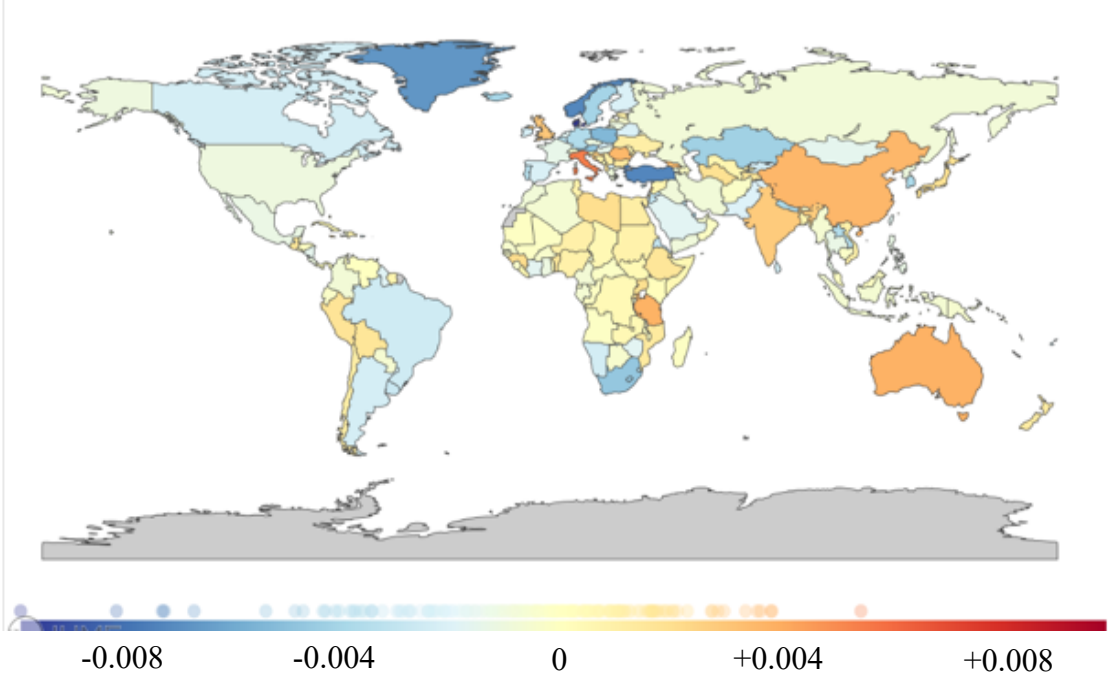
Women's Cardiovascular Health:

Extent of the Problem?

Prevalence of Cardiovascular Diseases in Women

Age-standardized CVD prevalence in women in 2019 (prevalence per 100,000)	Annual % change in CVD prevalence in women from 2010 to 2019

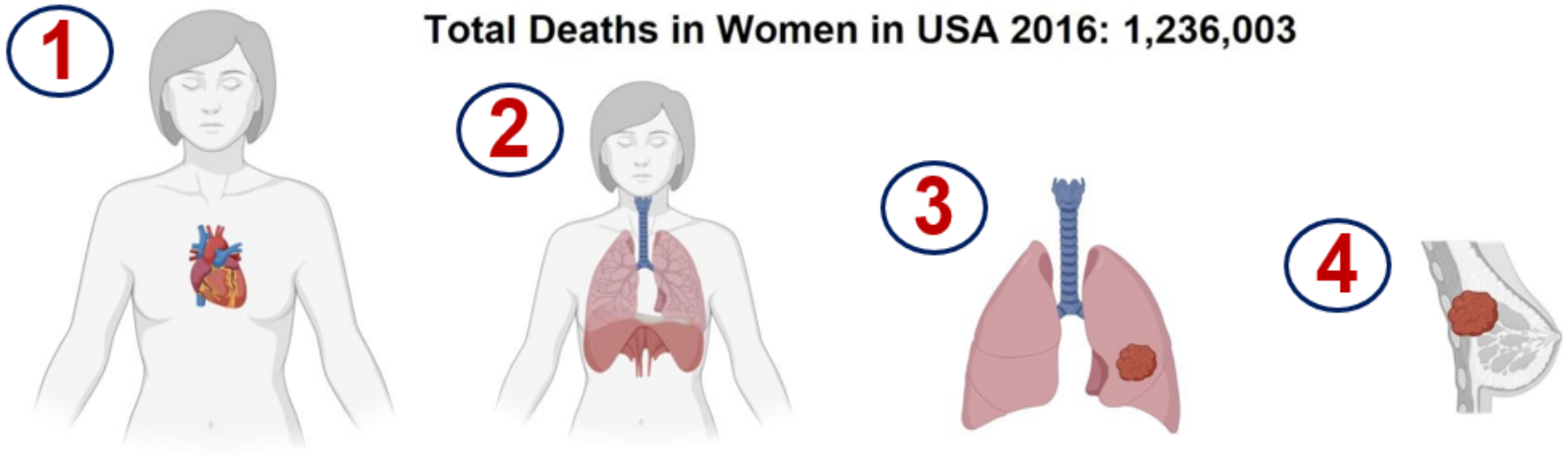




Globally CVD prevalence decreased between 1990 and 2010, but it slightly increased since 2010

Global Burden of Disease Study 2019 (GBD 2019) Results.
Seattle, United States: Institute for Health Metrics and Evaluation (IHME), 2020.
Available from http://ghdx.healthdata.org/gbd-results-tool

CVD is the Leading Cause of Mortality in Women



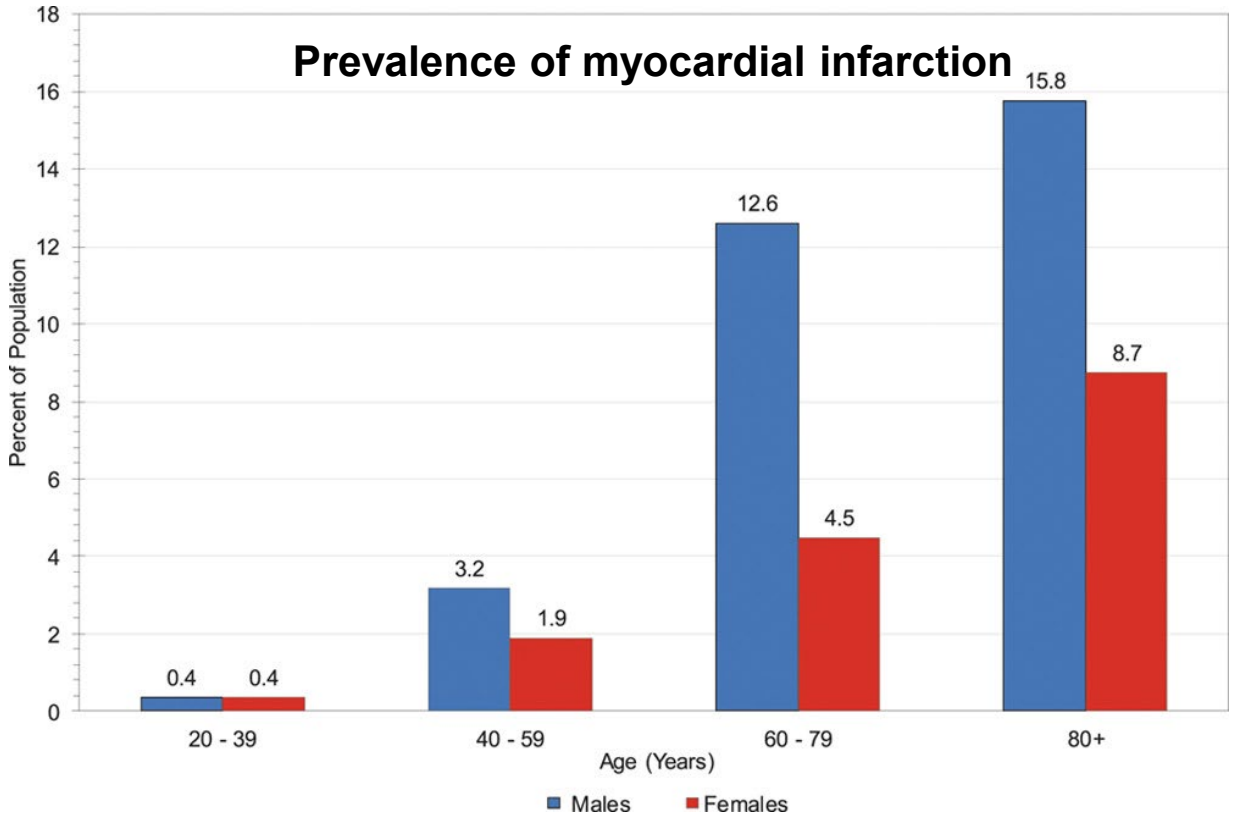
Cardiovascular disease 412,244 deaths	Chronic Lung Disease 81,551 deaths	Lung Cancer 70,500 deaths	Breast Cancer 40,920 deaths

With regard to cardiovascular disease subtypes, **ischemic heart disease is the most common cause of cardiovascular death in women** globally

Benjamin EJ et al. Circulation 2019

Prevalence of Acute Myocardial Infarction

Heart Disease and Stroke Statistics—2021 Update (Report from AHA)

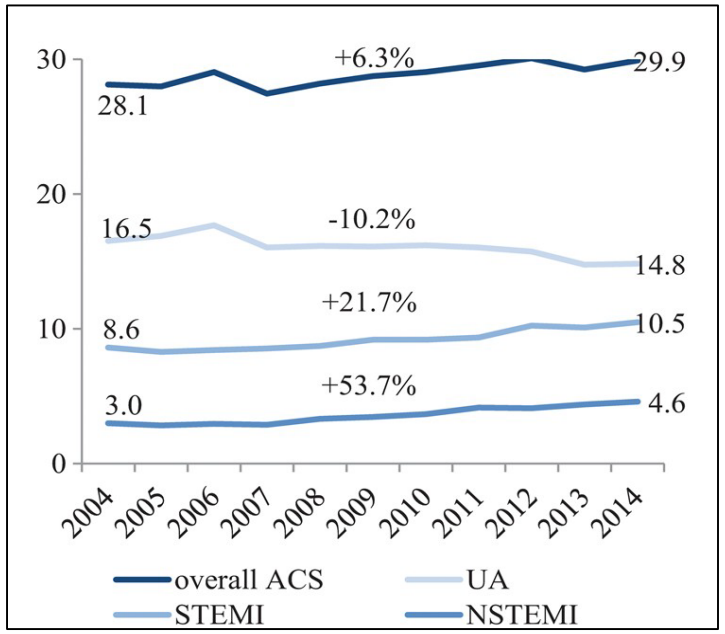


- The median survival time after a first MI is as follows: **at ≥45 years of age, 8.2 for males and 5.5 years for females.**
- Of those who have a first MI, the percentage with a recurrent MI or fatal CHD within 5 years is as follows: **at ≥45 years of age, 17% of males and 21% of females.**

Virani S et al Circulation. Circulation. 2021;143:e254–e743

There is an Increase in Myocardial Infarction in Young Women

French women <65 years of age



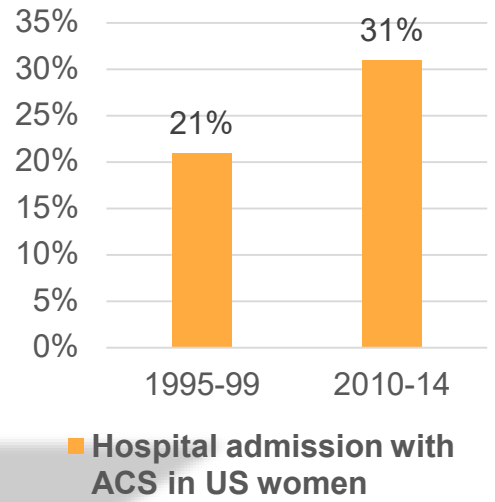
Hospital admissions with acute coronary syndrome in women younger than 55 years

INCREASE

D 21% in 1995–99

31% in 2010–14

Data from US

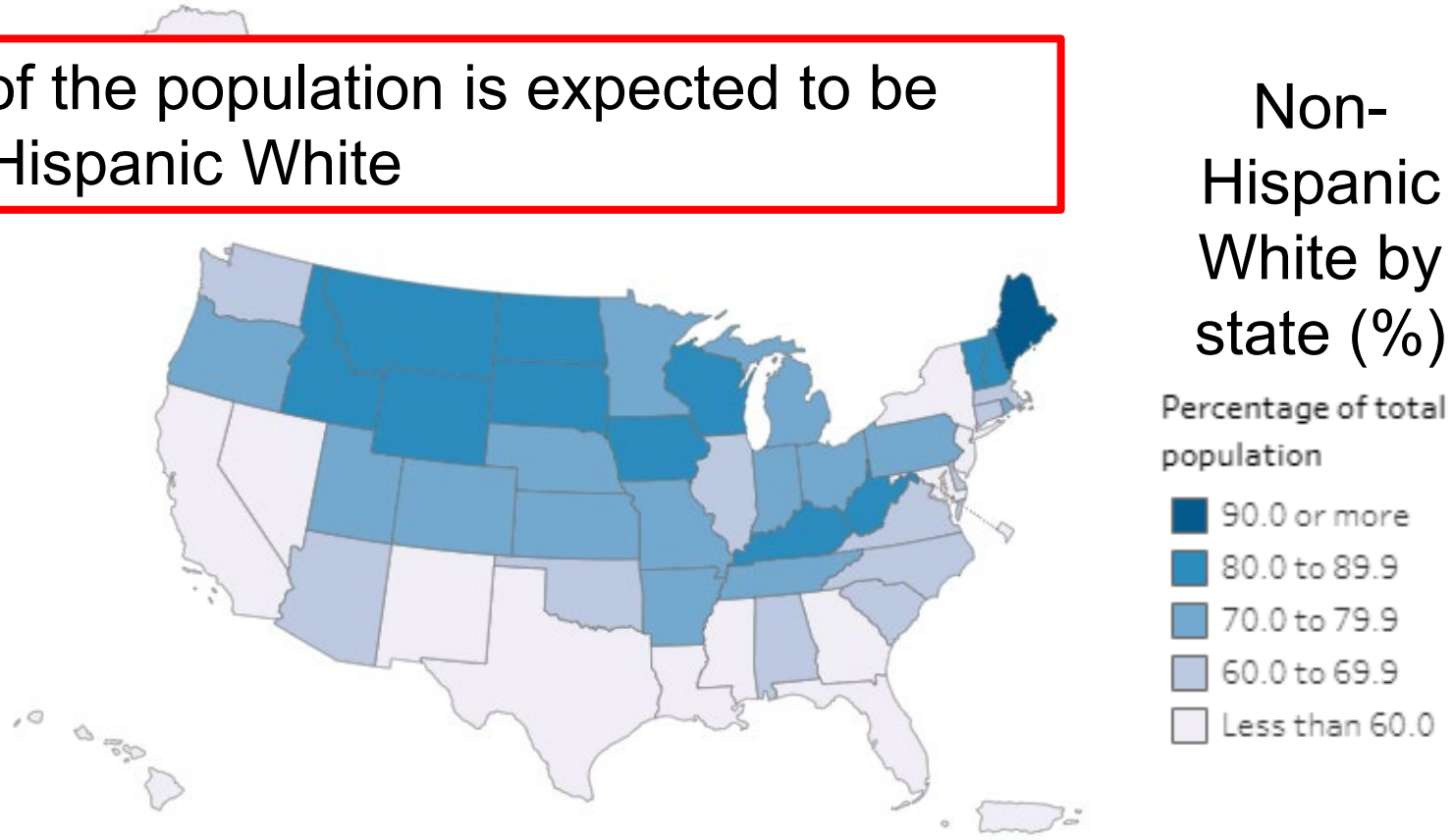


Gabet A et al., Eur Heart J 2017; Arora S et al., Circulation 2019

Not only gender disparities, but also ethnic/racial disparities exist!

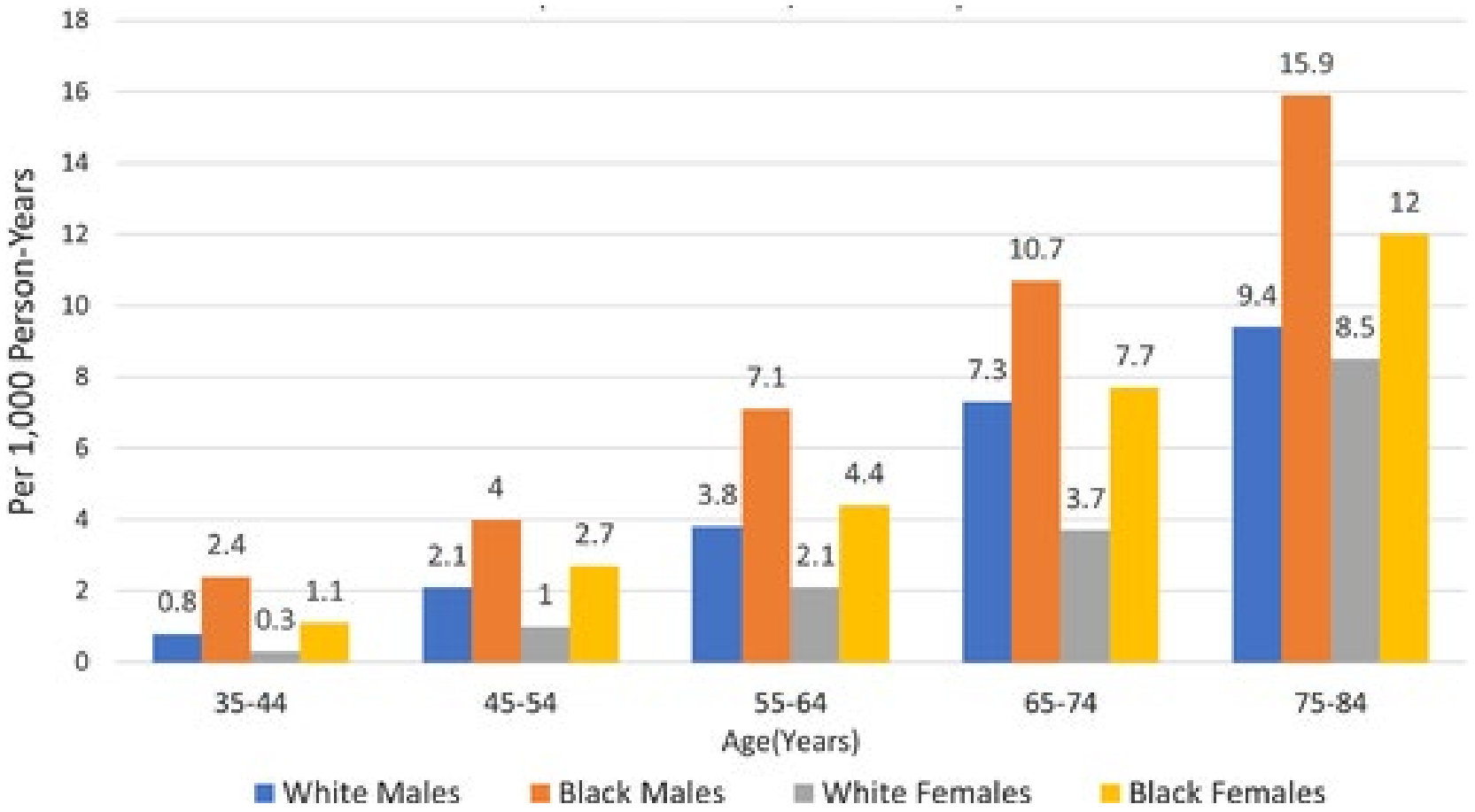
US 2020 Census: 38.4% are other than Non-Hispanic White

In 2045, >50% of the population is expected to be other than non-Hispanic White



Source: 2020 Census Redistricting Data (Public Law 94-171) Summary File at https://www.census.gov/library/visualizations/interactive/race-and-ethnicity-in-the-united-state-2010-and-2020-census.html

Incidence of myocardial infarction by age, sex and race



ARIC surveillance 2005-2014

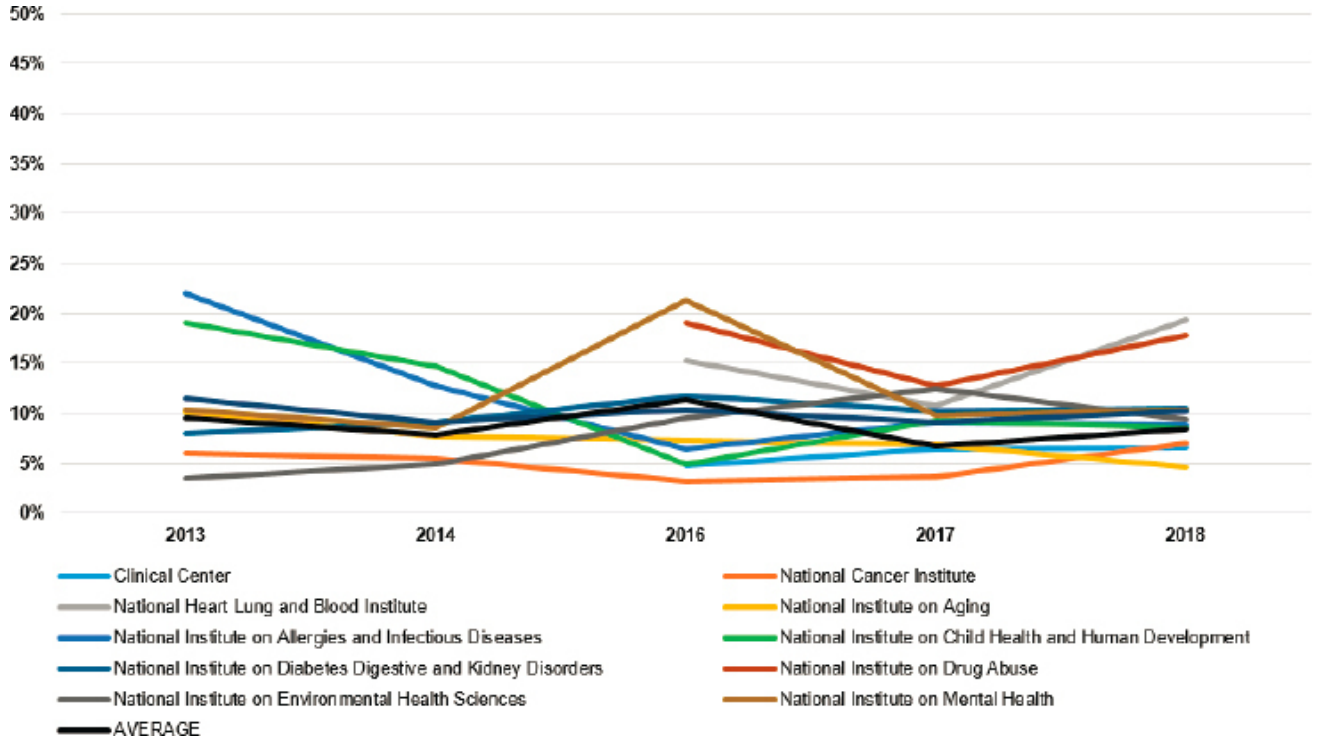
- Remarkably higher risk in black females and males
- Consistent across all ages

Grines CL et al. Catheter Cardiovasc Interv. 2021 Aug 1;98(2):277-294

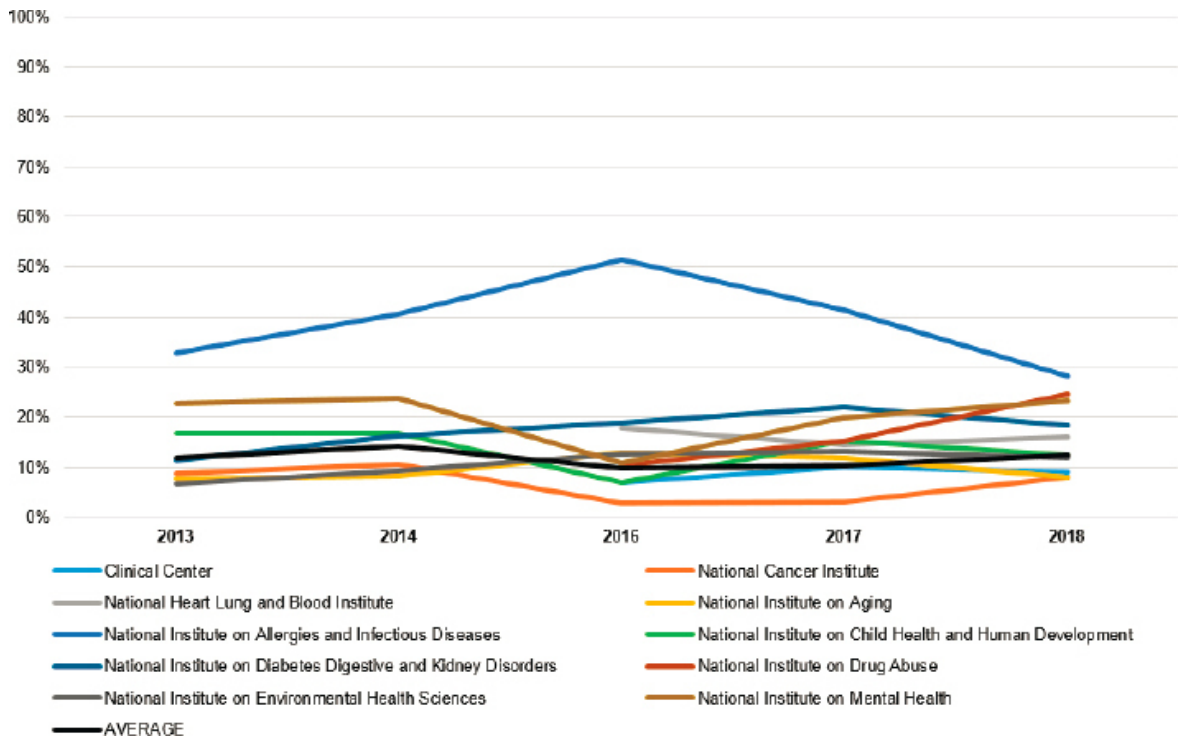
Diversity in RCTs

Enrollment of ethnic minorities in NIH clinical trials

Share of Hispanic participants in clinical trials by NIH institutes



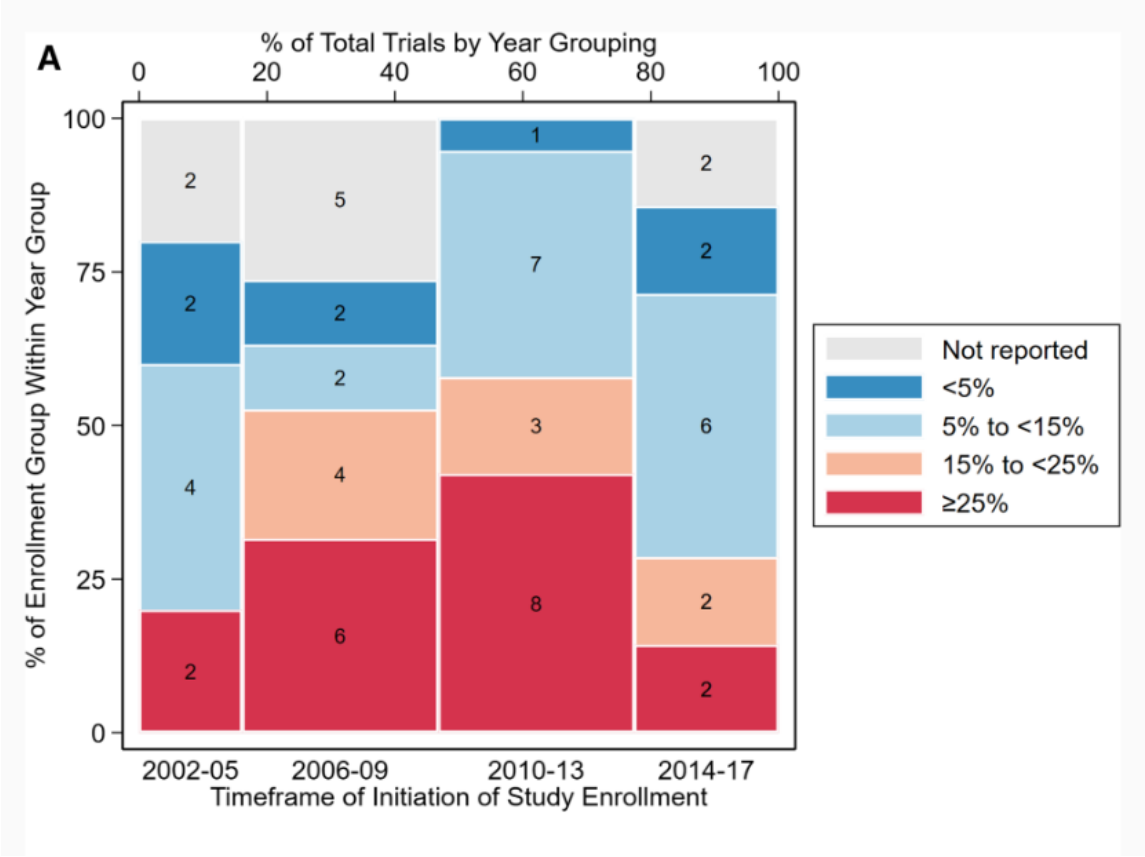
Share of African American/Black participants in clinical trials by NIH institutes



National Academies of Sciences, Engineering, and Medicine. 2022. ***Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups***

Rate of African American/Black participants in cardiovascular trials by time frame

Recruitment characteristics of NIH funded CVD trials (n=62 analysed from 2000-2019)



Number of clinical trials population composed of Black participants, by timeframe

- 46% of trials reported enrolling <25% Black participants
- No significant change in the recruitment of Black adults between 2002 and 2017

Prasanna A et al. J Am Heart Assoc. 2021 Sep 7;10(17):e021108.

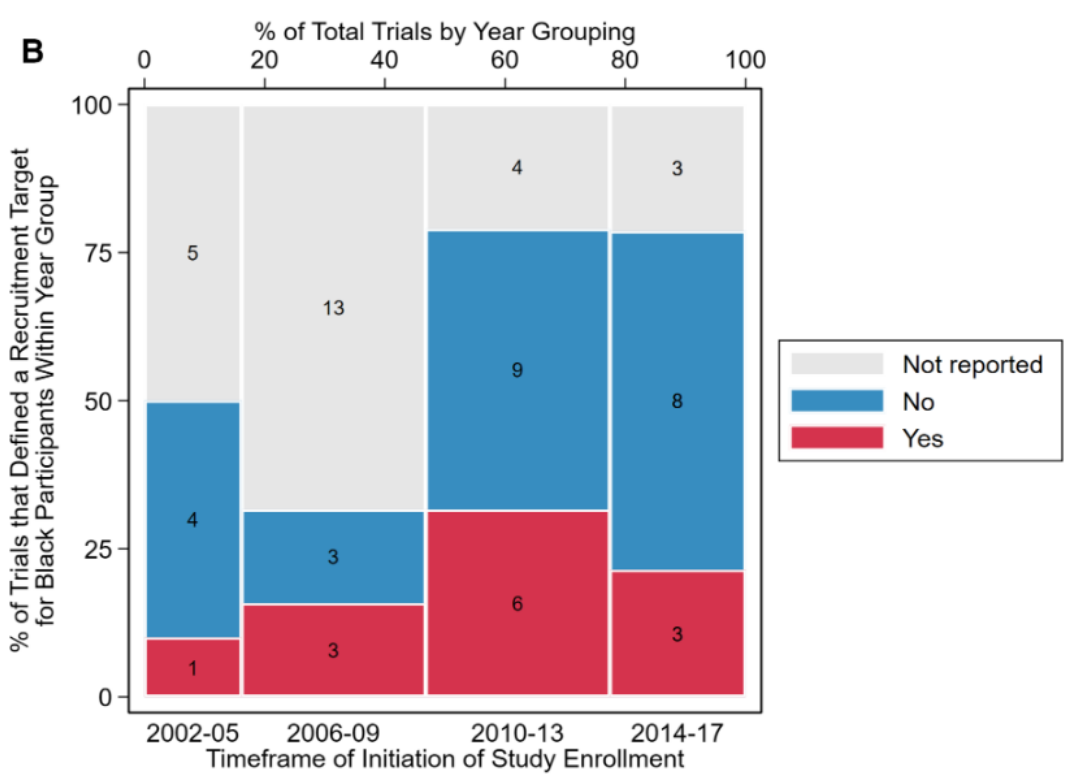
Setting and achieving recruitment goals for enrollment of Black participants

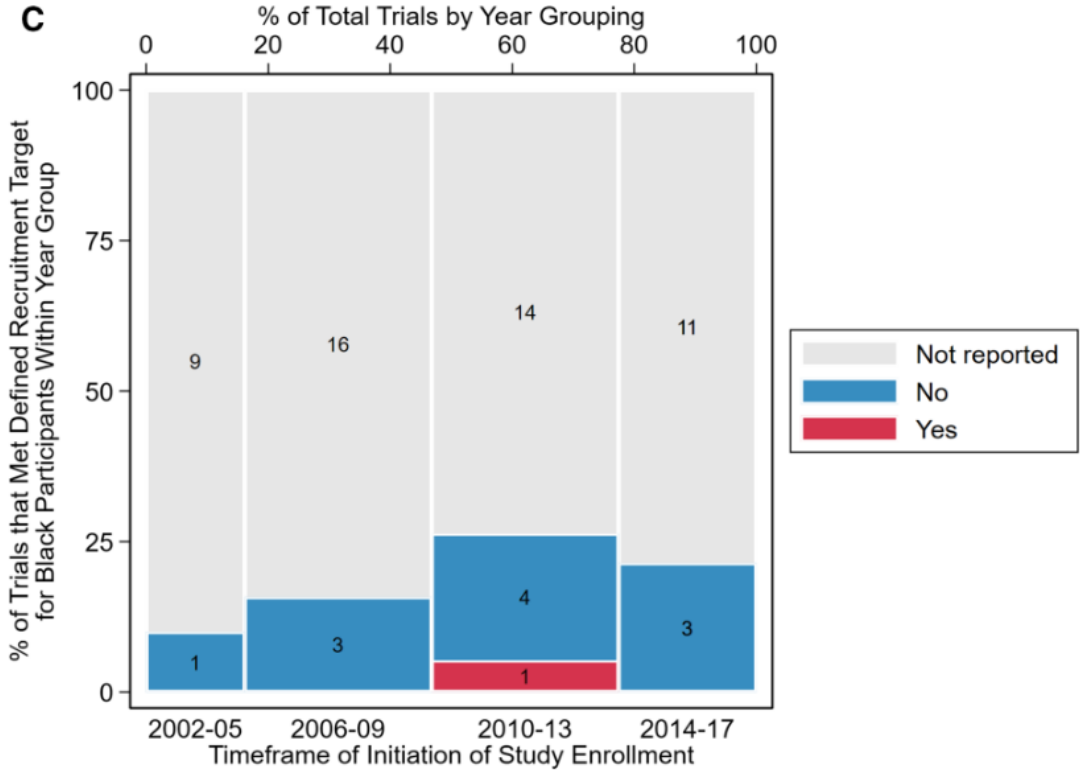
Rate of studies that defined recruitment target for Black participants, by timeframe

- Majority of trials do not define or report on recruitment targets for black participants

Rate of studies that achieved recruitment target for Black participants, by timeframe

- only 1 trial explicitly documented achieving recruitment goals for Black participants during this period





Prasanna A et al. J Am Heart Assoc. 2021 Sep 7;10(17):e021108.

Diversity in trials supporting FDA approval of cardiometabolic drugs

Findings:
35 novel drugs

Study Participants (n=296,163)
81% White
36% Women
4% Black
12% Asian
11% Hispanic/Latino

Women: underrepresented
(particip. to prev. ratio of 0.5 for HF, CAD)

No change in enrollment over 10 years

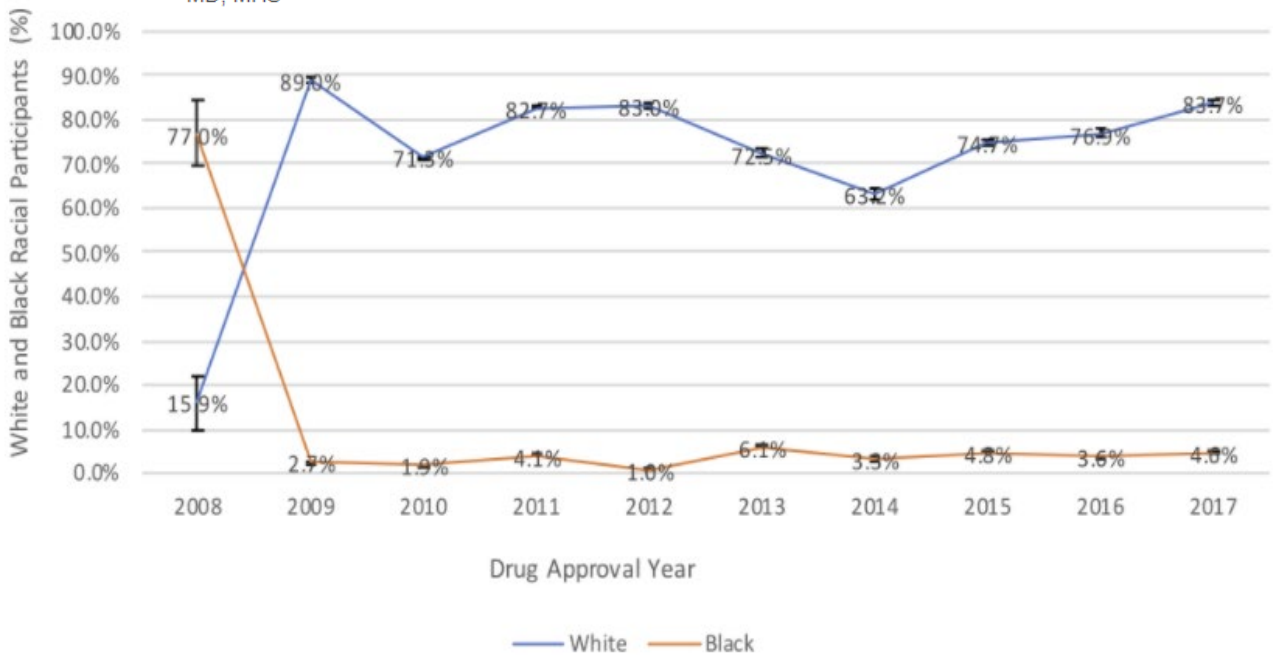
EPIDEMIOLOGY

JAHA 2020

American Heart Association.

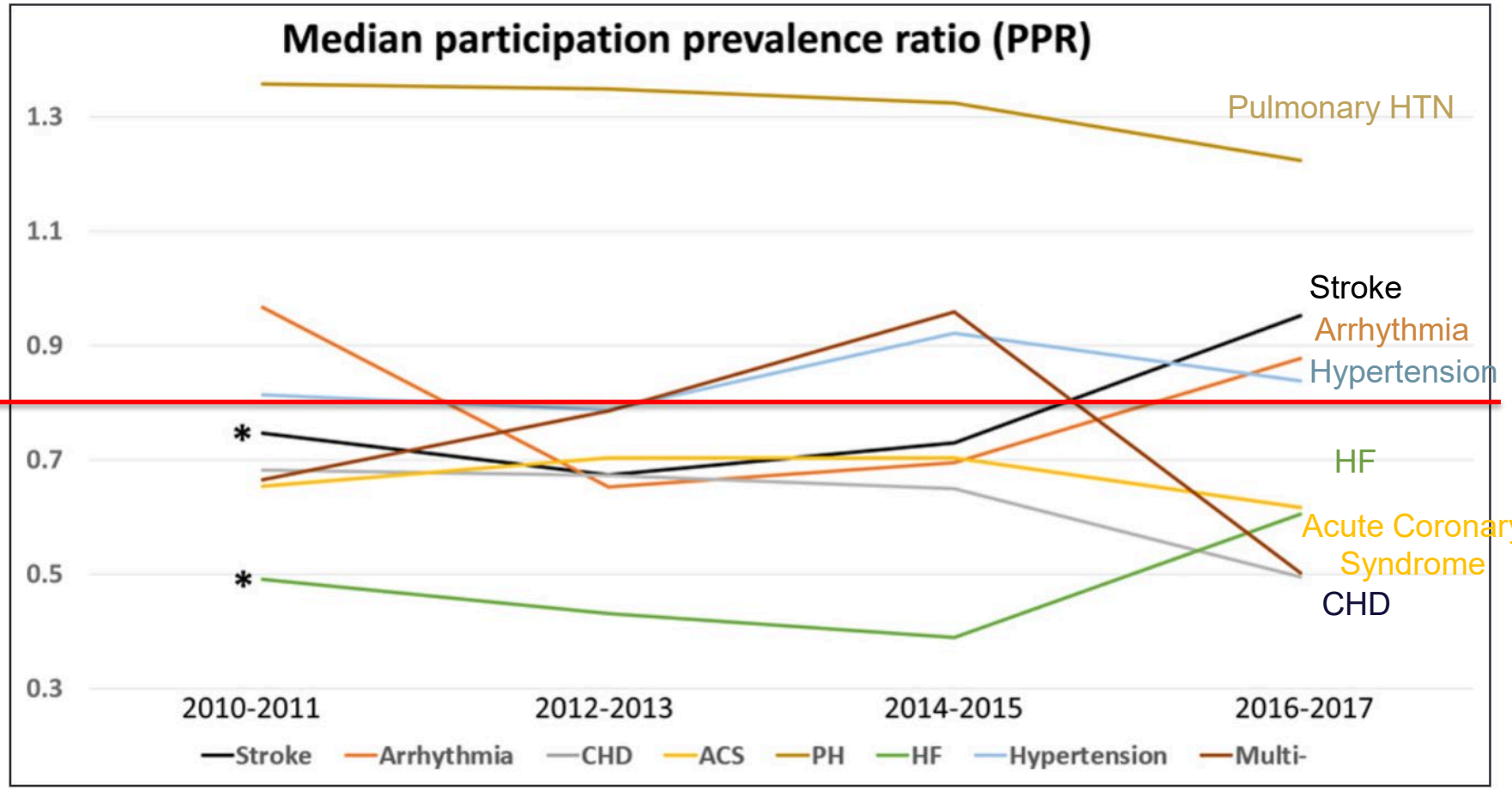
Ten-Year Trends in Enrollment of Women and Minorities in Pivotal Trials Supporting Recent US Food and Drug Administration Approval of Novel Cardiometabolic Drugs

Muhammad Shahzeb Khan, MD; Izza Shahid, MBBS; Tariq Jamal Siddiqi, MBBS; Safi U. Khan, MD; Haider J. Warraich, MD; Stephen J. Greene, MD; Javed Butler, MD, MPH, MBA; Erin D. Michos, MD, MHS



Khan MS et al. J Am Heart Assoc. 2020 Jun 2;9(11):e015594.

Participation-prevalence ratio of women in 740 CVD trials between 2010 and 2017



Women have been under-represented in heart failure, acute coronary syndrome, coronary heart disease, stroke, and arrhythmia trials.

PPR of <0.8 indicates underrepresentation in relation to disease prevalence

Jin X et al. Circulation. 2020 Feb 18;141(7):540-548.

Diversity in RCTs - Why does it matter?

Generalizability of results

Ethical considerations: provide equal opportunities

Address health disparities

Practice precision medicine

Detect potential differences in safety and efficacy

Tailor practical guidelines

Improve public health outcomes

Strategies to increase the proportion of women in clinical trials

Be Inclusive
- Avoid upper and lower age limits in exclusion criteria for enrolment in trials

Meet women where they are
- Target outreach in community settings frequented by women
- Involve primary care physicians and family members
- Provide education and information about the risk but also the benefits of participation

Exchange knowledge
- Educate recruiting personnel on importance of enrolling women
- Share experience of enrolling women after each study
- Conduct routine surveys on motivations for participation and non-participation in trials

Remove barriers
- Arrange childcare and free transportation
- Offer flexible hours and at-home follow-up

Vogel B et al. Lancet. 2021 Jun 19;397(10292):2385-2438.

Strategies to increase diversity in CVD trials

1: Ensure your eligibility criteria and recruitment pathway do not limit participation in ways you do not intend
Ensure that eligibility criteria do not disproportionally affect the ability of ethnic minority groups to take part in the trial.

2: Ensure your trial materials are developed with inclusion in mind
Consider language and not just in written form but also verbal and expressed in other ways.

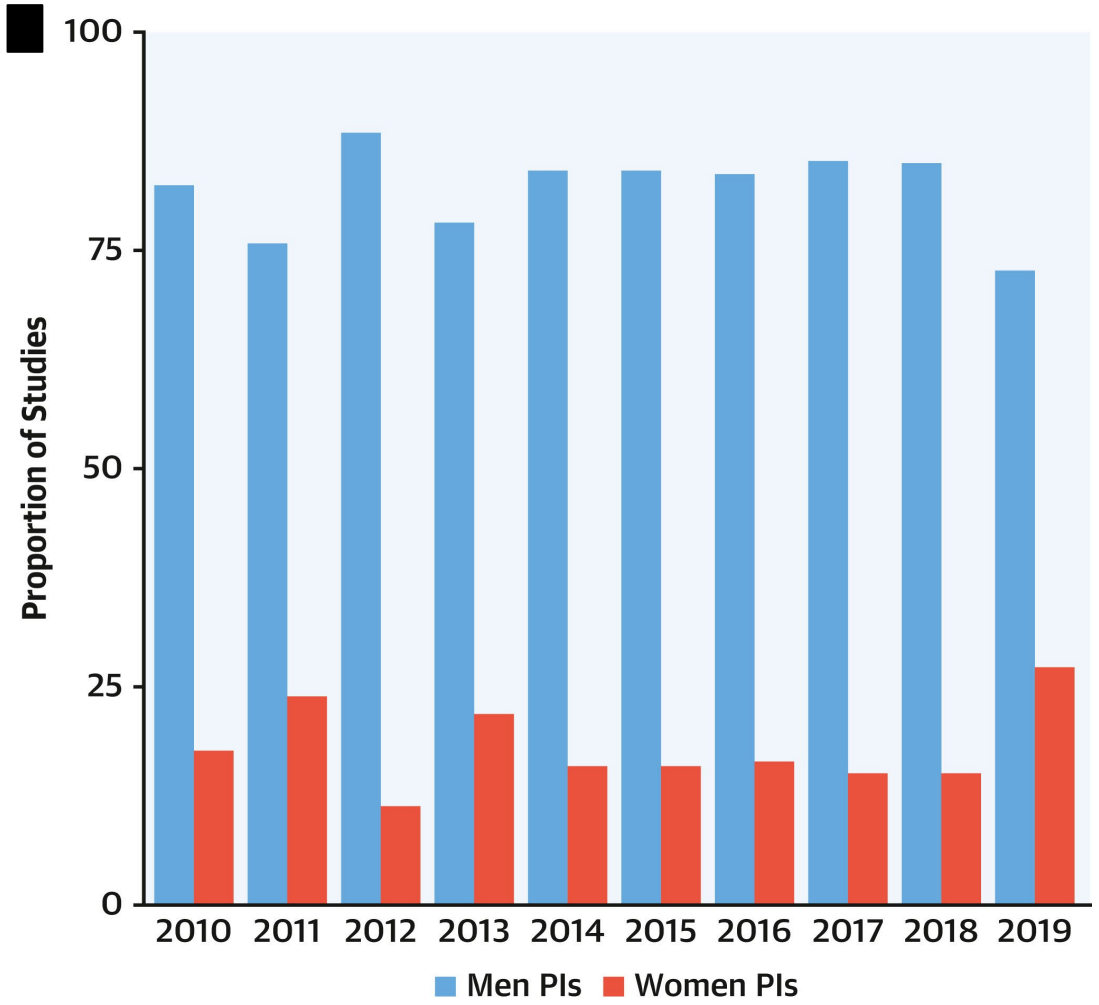
3: Ensure trial staff are culturally competent
Provide support and training to all staff on cultural competency to avoid stereotypes and increase their confidence to engage with different ethnic groups.

4: Build trusting partnerships with community organisations that work with ethnic minority groups
Spend time to build relationships with local community organisations and ensure you allocate time and resources to this when designing the trial.

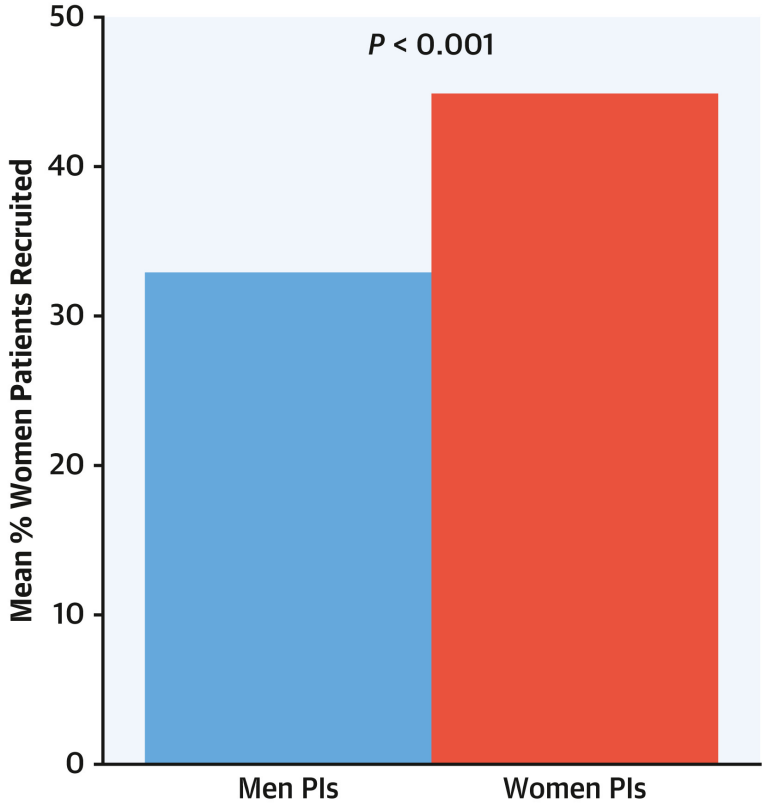
Dawson S et al. Trials. 2022; 23: 672

Michos E et al. Am J Prev Cardiol. 2021 Aug 20:8:100250

Temporal trends in principal investigator gender and association with patient diversity

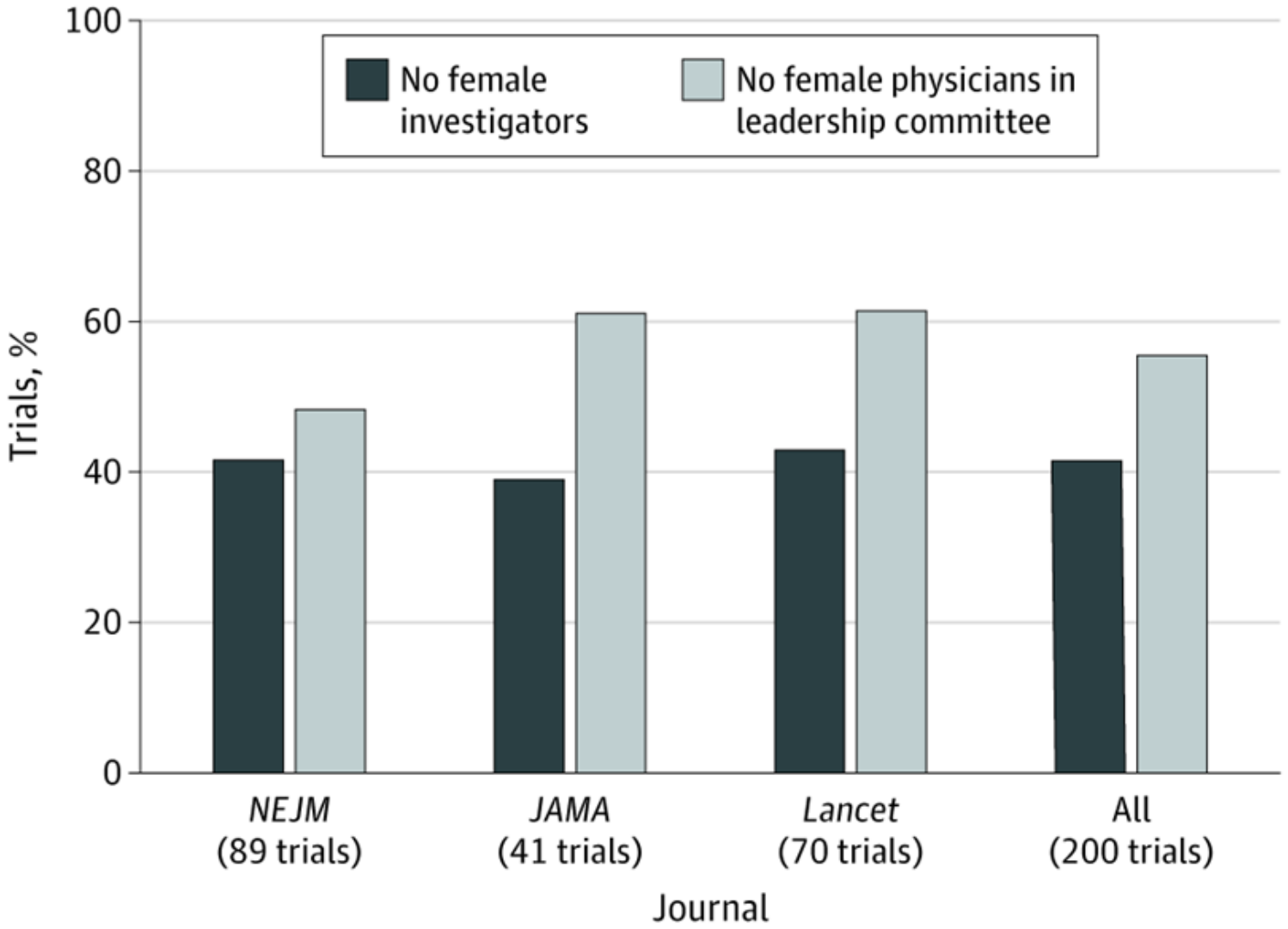


Female PIs lead to a higher rate of female recruitment!



Yong C et al. J Am Coll Cardiol. 2023 Jan 31;81(4):428-430.

Representation of Women in CVD Clinical Trial Leadership



- 56% of leadership committees had no female representation.
- 42% of trials had NO women investigators.
- 9% of trial publications had women in first authorship position.

Deny K et al. JAMA Intern Med. 2020;180(10):1382-1383.

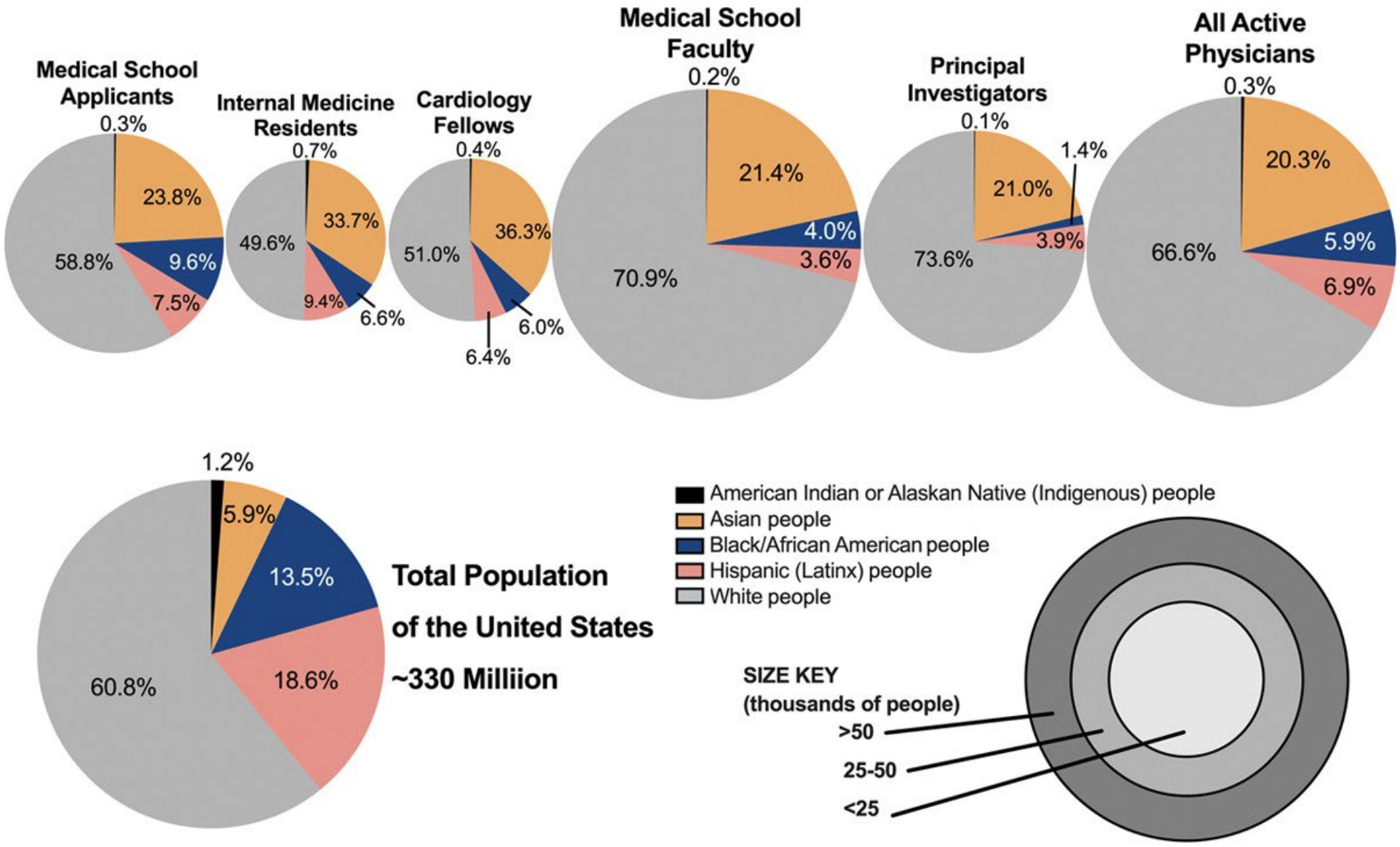
Gender Differences in Grant Funding

- *Women are **less frequently mentored** than men and experience **less sponsorship** for NIH Mentored Career Development grants.*
- *Because first author roles do not track into later senior authorships as often for women, they represent **only 1 in 10 lead authors** of cardiovascular trials published in high-impact journals.*
- ***More than one-half** of cardiovascular trials published in 3 high-impact factor journals between 2014 and 2018 **lacked women investigators** on their executive committees.*

Woodruff T et al. JAMA. 2019 Aug 13;322(6):579-580.
Van Spaal HGC et al. J Am Coll Cardiol. 2021 Jun 15;77(23):2960-2972.

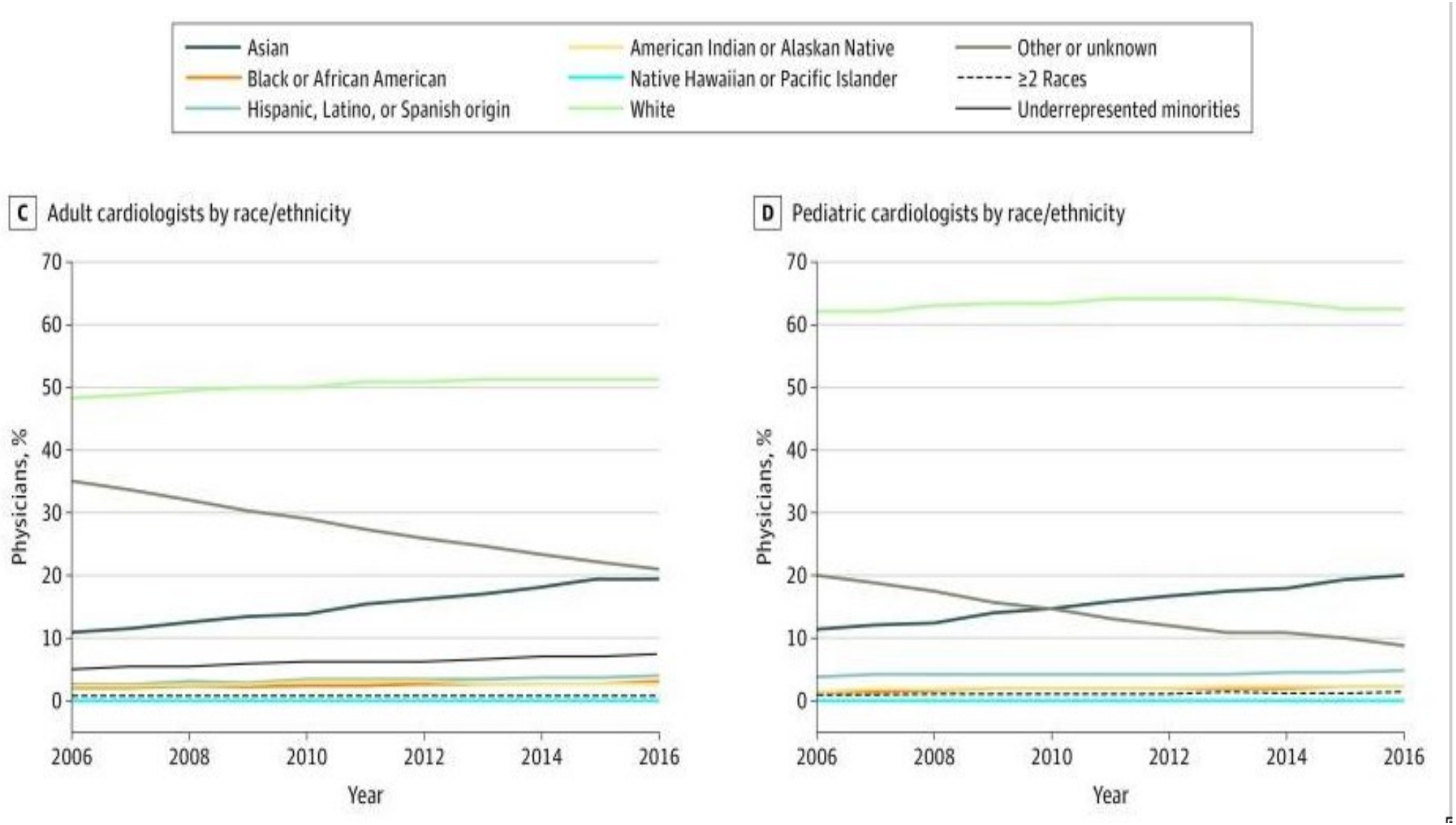
Workforce Considerations

Contemporary trends in underrepresentation in medicine



Johnson AE et al. J Am Coll Cardiol. 2021 Apr 20;77(15):1934-1937.

Cardiologists by race in the US: Temporal trends



Mehta LS et al. JAMA Cardiol. 2019 Oct; 4(10): 1029–1033.

Representation of American race groups in the cardiology workforce

Data from US Census and Association of American Medical Colleges (AAMC)

US Federal Definition	AAMC Terminology	Terminology used in this Review	% of US Population	%of US Adult Cardiology Physician Workforce	% Difference
American Indian or Alaska Native.	Native American	Indigenous	1.3	0.2	**−1.1**
Asian.*	Asian or Pacific Islander	--	5.9	19.9	**+14.0**
Black or African American.	Black	Black	13.4	3	**−10.4**
Hispanic or Latino.	Latino/Hispanic	Latinx	18.5	4.2§	**−14.3**
Native Hawaiian or Pacific Islander.*	Native Hawaiian	--	0.2	Data not available	**Unknown**
White.	White	White	60.5	51.2	**−9.3**

Johnson AE et al. J Am Coll Cardiol. 2021 Apr 20;77(15):1934-1937

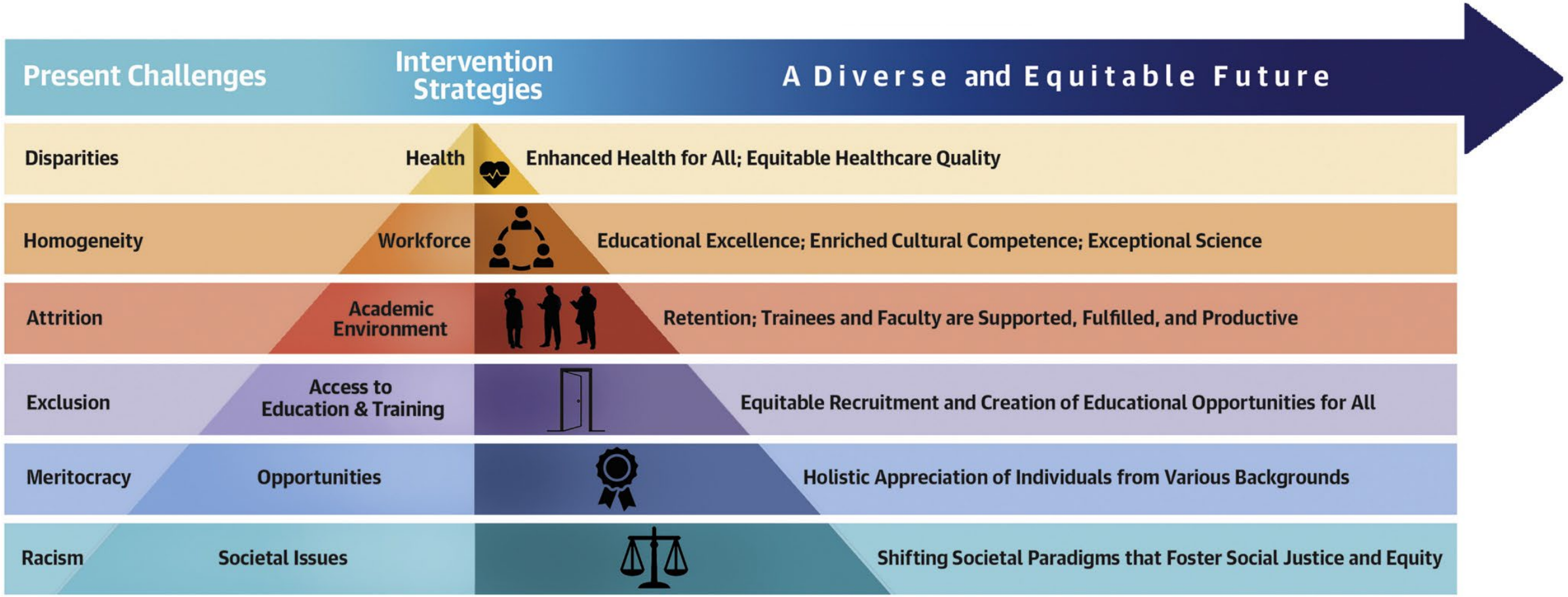
Women in cardiovascular medicine

Women are only

- **18% of cardiology fellows**
- **10-15% of practicing cardiologists**
- **4% of interventional cardiologists**

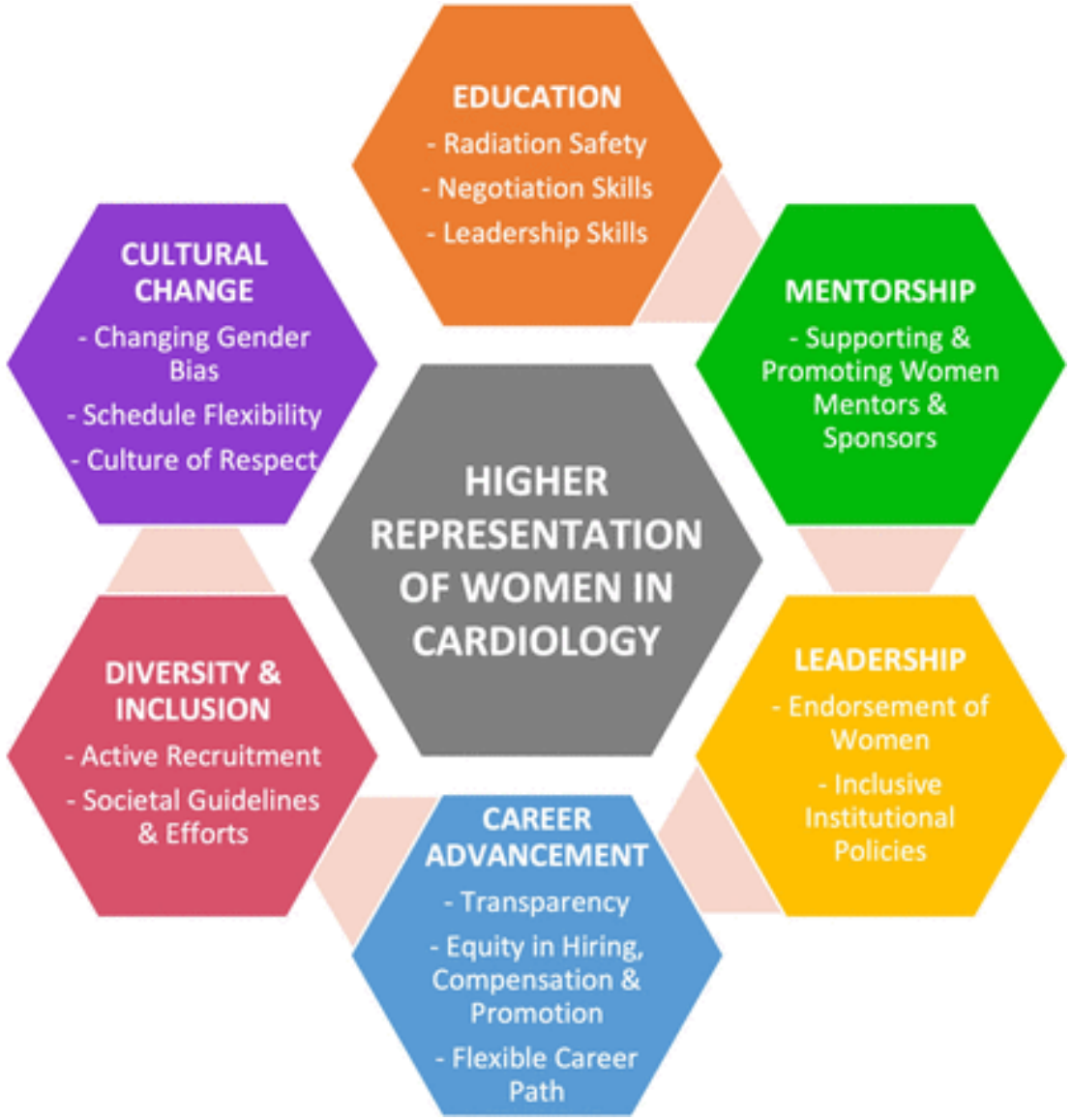
https://www.acc.org/Membership/Sections-and-Councils/Medical-Residents/Women-in-Cardiology

Optimizing CV health requires diversification of the cardiology workforce



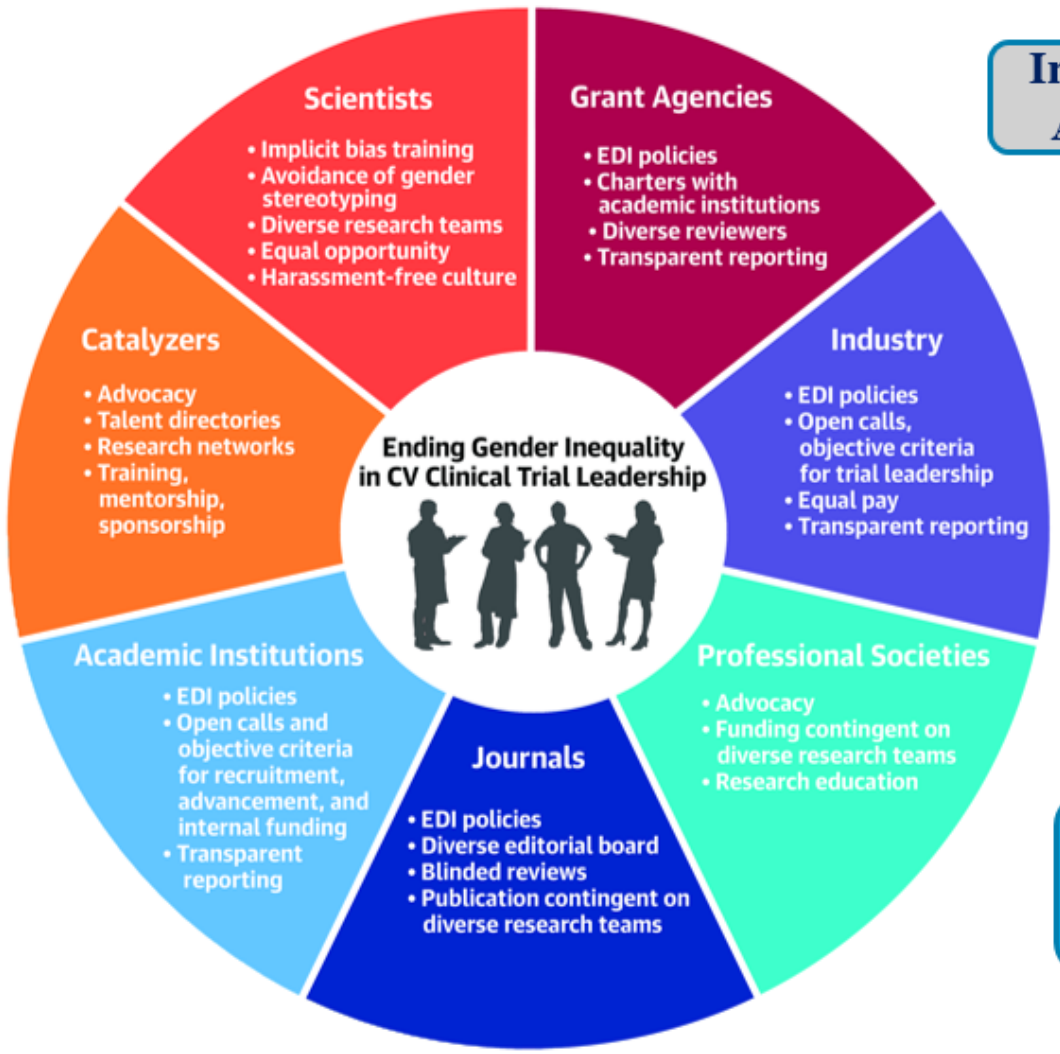
Johnson AE et al. J Am Coll Cardiol. 2021 Apr 20;77(15):1934-1937

Six pillars of increasing the proportion of women in cardiology



Eshtehardi P et al. Open Heart. 2022 Feb;9(1):e001967

How to improve (gender) diversity in clinical trial leadership?



Implicit Bias Awareness

Avoidance of Gender Stereotyping & Language Asymmetries

Mentorship to Women and Under-represented Groups

Equal Opportunity for Team Members

Diversity in Research Teams

Harassment-Free Culture

Leadership and Institutional Accountability

Van Spall HGC et al. J Am Coll Cardiol. 2021;77(23):2960-2972

Underrepresentation of women and minorities in cardiology and underrepresentation of women and minorities in cardiovascular research go hand in hand!

Women as One

Proactive Solutions for Diversifying Clinical Trial Leadership

Our Story

Women as One was founded in 2019 by **Dr. Roxana Mehran** & **Dr. Marie-Claude Morice**, two internationally recognized leaders in cardiovascular care and research.

Our Mission

Our mission is to promote talent in medicine by offering women physicians unique professional opportunities. By doing this, we aim to build a more inclusive, diverse and just workforce in medicine.

https://womenasone.org

CLIMB Research Scholars

WOMEN AS ONE
promoting talent in medicine

Uplifting women in clinical trial leadership

Congratulations to the 2023 Awardees

Erin Bohula
MD, PhD
Harvard Medical School, United States

Caroline Coats
MBBS, MSc, PhD
Queen Elizabeth University Hospital, Scotland

Sonali Gnanenthiran,
MD, PhD
Concord Hospital, Australia

Join the Talent Directory to be eligible for the 2024 program

www.womenasone.org/talent-directory

With thanks to 2023 program partners CVCT ESPERION | REACHING GOALS

THE 2024 ESCALATOR AWARDS

- **Gain professional visibility with targeted financial support**
- **Access to mentorship and exclusive networking opportunities**

Focus on mentorship for 2024

- Pairs fellows-in-training (mentees) to women with more than 10 years of professional experience (mentors).
- Together, the match will develop a project that can be carried out over the course of the 12-month award cycle.

Take your career to the next level

Applications open January 2024

The Talent Directory

The Talent Directory is a global community of **2300+** women cardiologists.

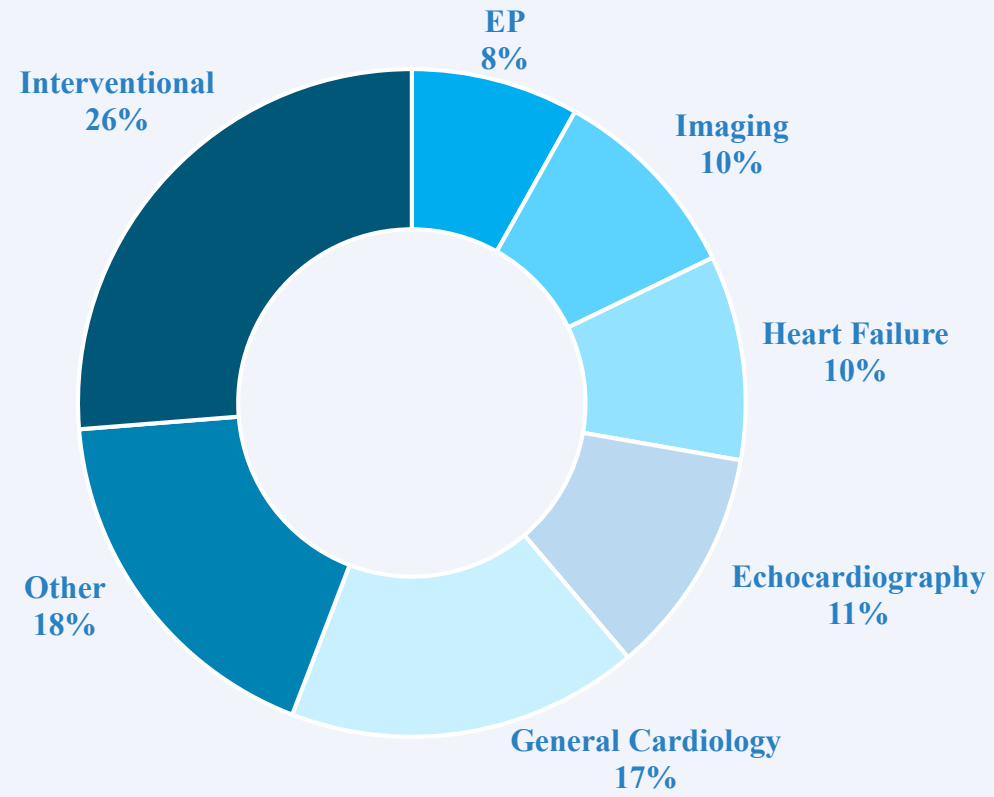
For women physicians, the Talent Directory unlocks professional advancement opportunities.

For organizations, the Talent Directory provides access to the insights and qualifications of a global pool of women physicians.

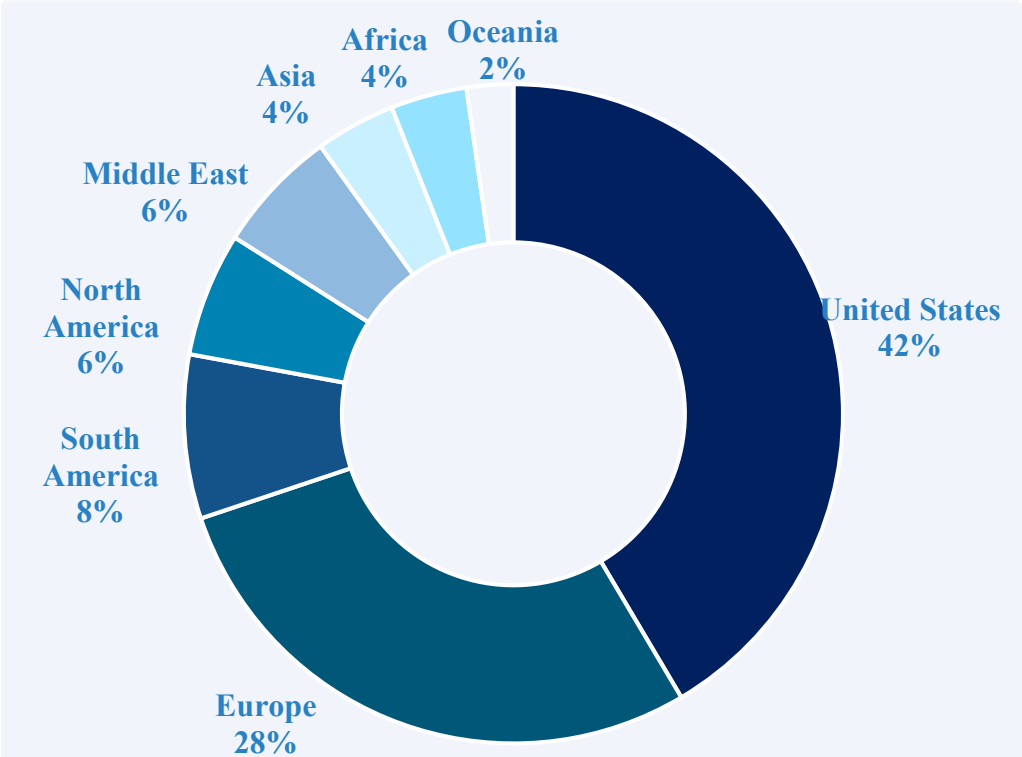
Breakdown of the Talent Directory

2345 total registrants
99 countries represented
Full CVs collected, sortable data

Subspecialty

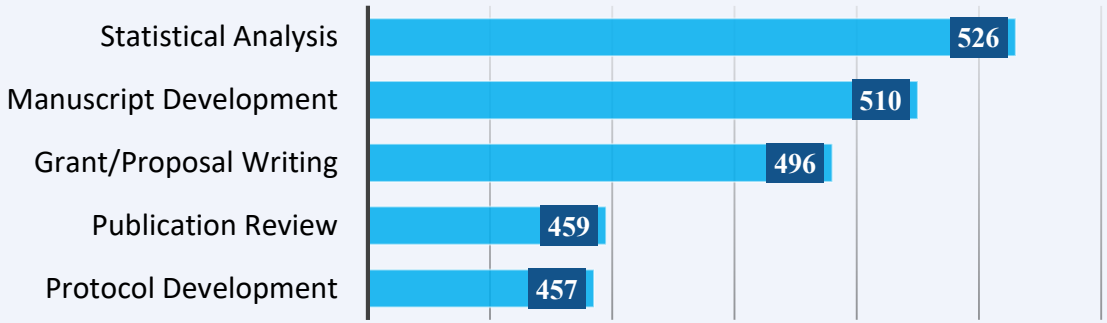


Region



Researcher Registrant Snapshot

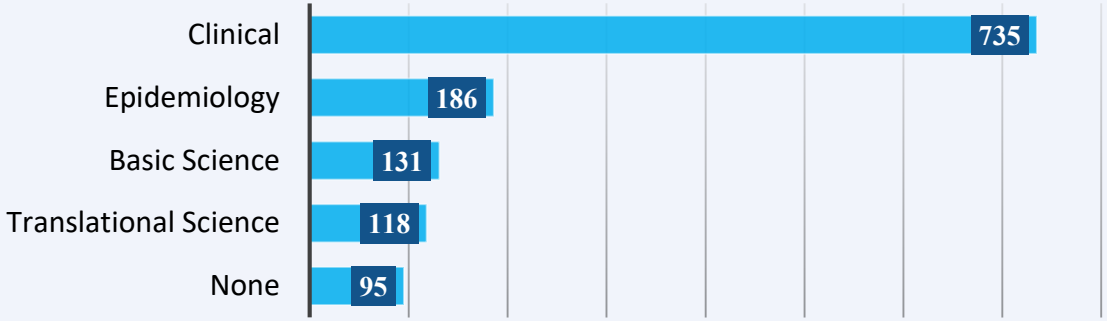
Research Topic Interests



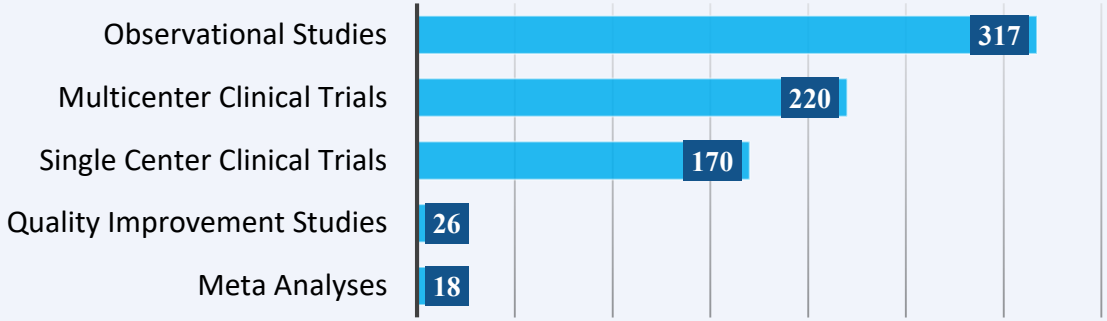
1017 Completed Research Profiles

- 222 registrants have Clinical Trial Leadership Experience.
- 435 registrants are interested in Clinical Trial Leadership.

Research Type



Clinical Research Type



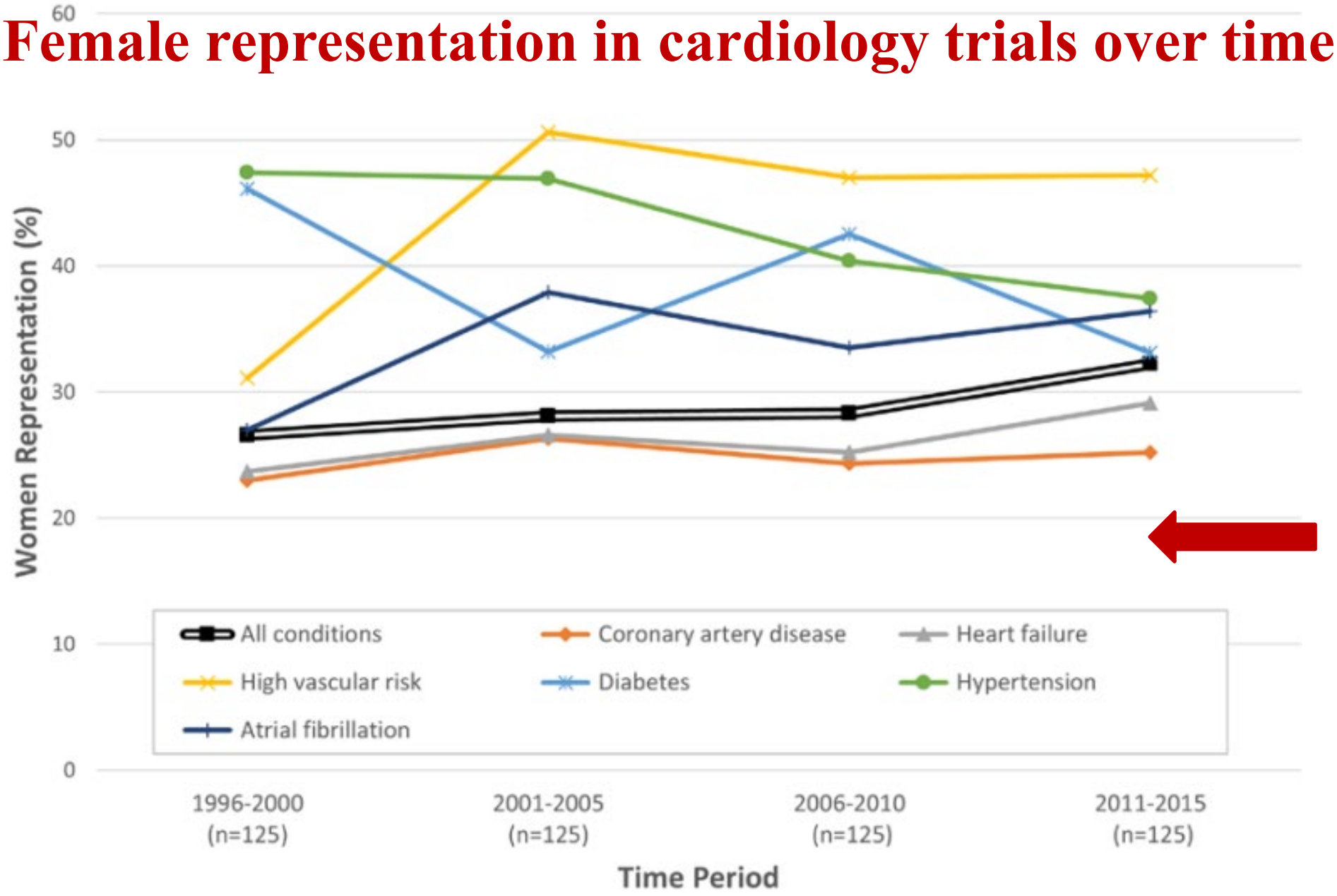
Women as One Institute for Research Innovation

Increasing and enhancing the participation of women within cardiovascular clinical research.

- ✓ Training, identification & qualification of women investigators
- ✓ Funding & promoting women researchers
- ✓ Consultancy services to increase representation of women in trials
- ✓ De novo study development
- ✓ Development & dissemination of best practices

COMING IN 2024

Female representation in cardiology trials over time



Nguyen QD et al. Circ Cardiovasc Qual Outcomes. 2018

Colchicine in patients with chronic coronary syndromes:

LODOCO

Nidorf SM et al. N Engl J Med 2020;383:1838-47

Table 1. Characteristics of the Trial Patients at Baseline.*

Characteristic	Colchicine (N=2762)	Placebo (N=2760)
Age — yr	65.8±8.4	65.9±8.7
Female sex — no. (%)	457 (16.5)	389 (14.1)
Country — no. (%)		
Australia	951 (34.4)	953 (34.5)
The Netherlands	1811 (65.6)	1807 (65.5)

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Nidorf SM et al. N Engl J Med 2020;383:1838-47

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Country — no. (%)		
Australia	951 (34.4)	953 (34.5)
The Netherlands	1811 (65.6)	1807 (65.5)

4S study:

Pedersen TL, et al Lancet 1994

	Placebo (n=2223)	Simvastatin (n=2221)
No (%) of patients		
Male	1803 (81)	1814 (82)
Female	420 (19)	407 (18)
Age ≥60 yr	1126 (51)	1156 (52)

A Placebo-Controlled Trial of Percutaneous Coronary Intervention for Stable Angina

NEJM nov 2023 ORBITA-2

Characteristic	PCI (N=151)	Placebo (N=150)	Overall (N=301)
Age — yr	65±9	64±9	64±9
Male sex — no. (%)	120 (79)	118 (79)	238 (79)

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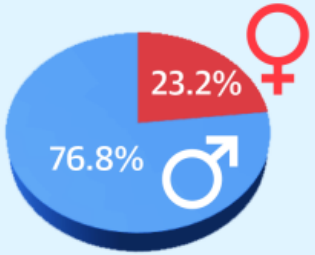
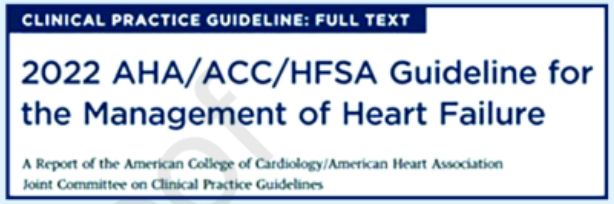
33 randomized clinical trials

Searched 4 academic databases for randomized clinical trials reporting interventions resulting in reduced mortality or hospitalization for heart failure (1995-2021)



104,972 total enrolled trial participants

31 of the 33 randomized clinical trials were mentioned

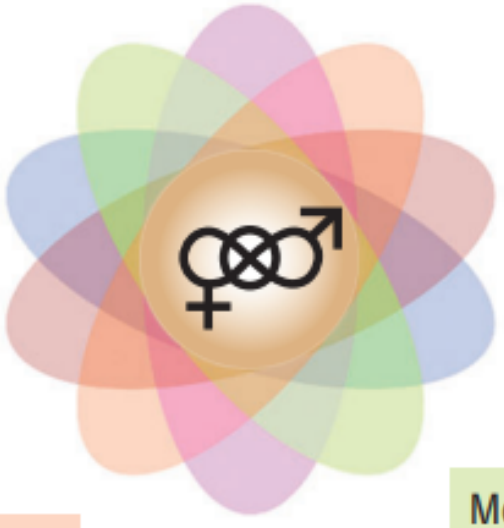


Representation of women in heart failure with reduced ejection fraction trials

Funding source:	Industry-funded trials	>	Government-funded trials
Enrollment region:	North American and multiregional trials	>	European trials
Temporal trends:	Did not improve over time		

Ekpo E et al JACCADV 2023

Figure 4. Parameters Through Which Sex May Affect an Individual's Response to Pharmaceuticals



Absorption
- Enterohepatic and renal handling
- Gastric enzymes
- Pulmonary function
- Transport proteins

Distribution
- Body fat composition
- Cardiac output, regional blood flow
- Total blood, plasma, and RBC volumes
- Total body, intracellular, and extracellular water

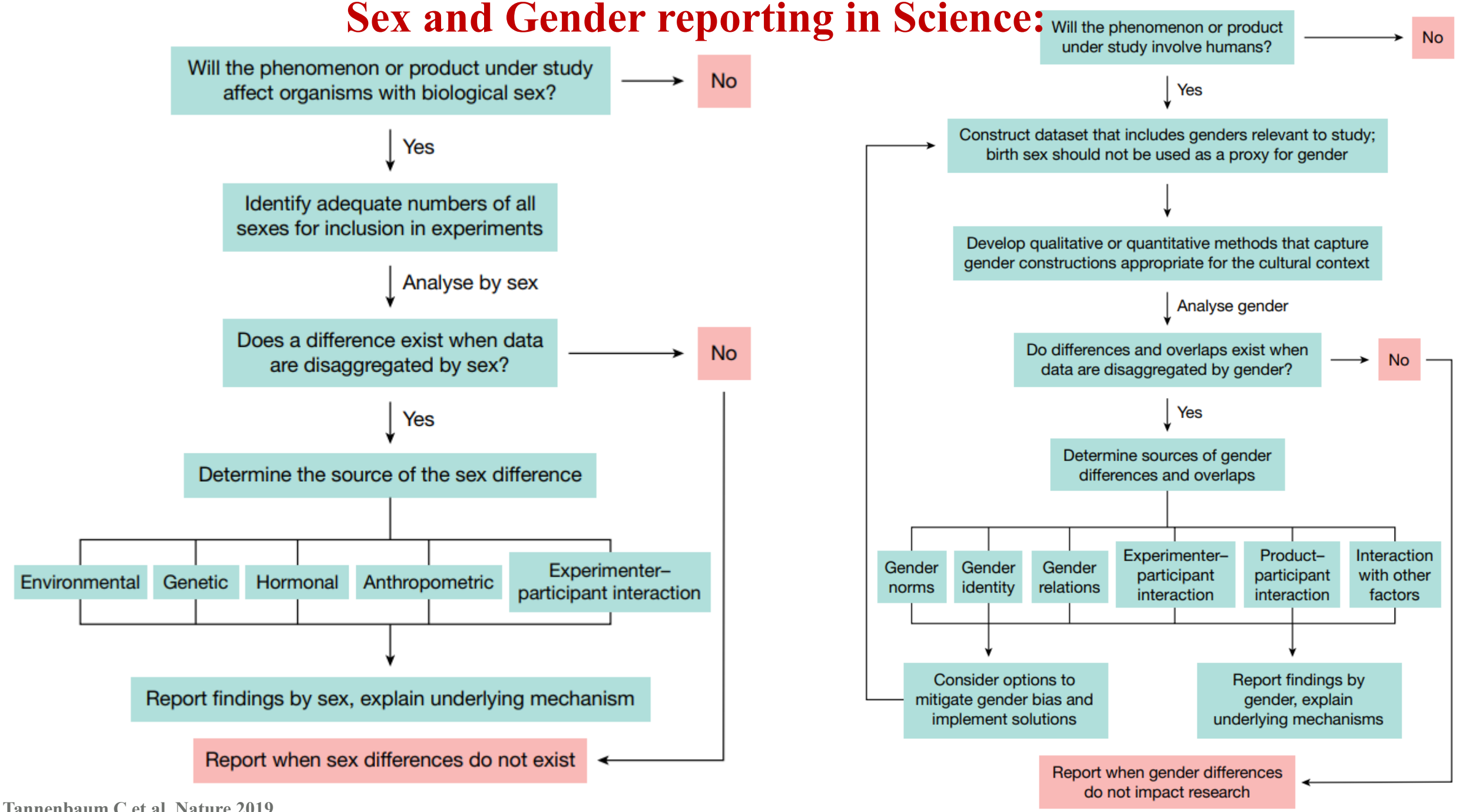
Pharmacodynamics
- Membrane receptor sensitivity
- Interactions with macromolecules (eg, hormones, enzymes)
- Target organ response, adverse events

Metabolism
- Dose
- Lipid solubility
- Protein binding and cytochromes P450
- Route of exposure

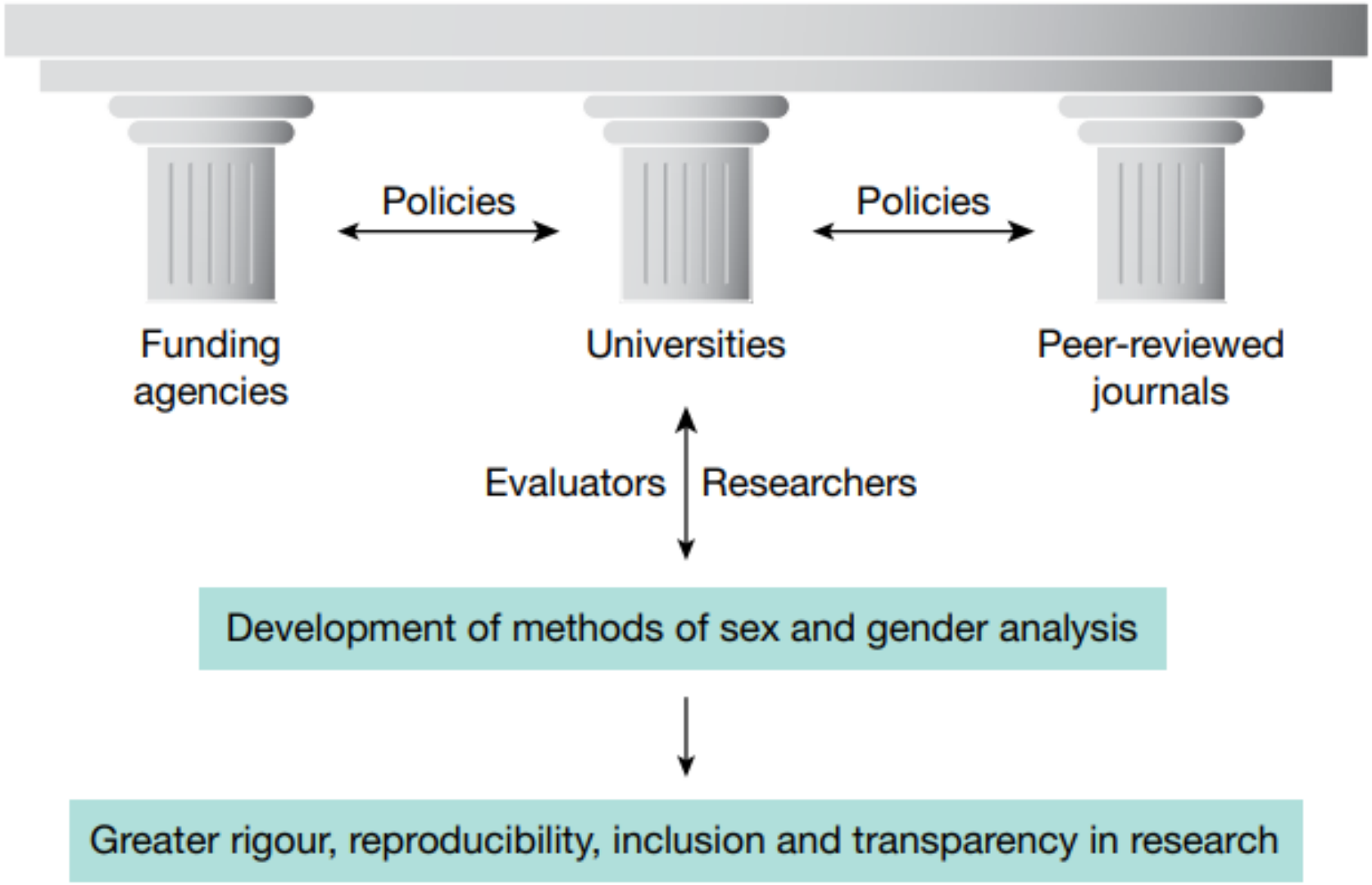
Elimination
- Glomerular filtration rate
- Renal blood flow
- Tubular secretion, reabsorption

Bartz D et al. JAMA Intern Med. 2020;180(4):574-583

Sex and Gender reporting in Science:



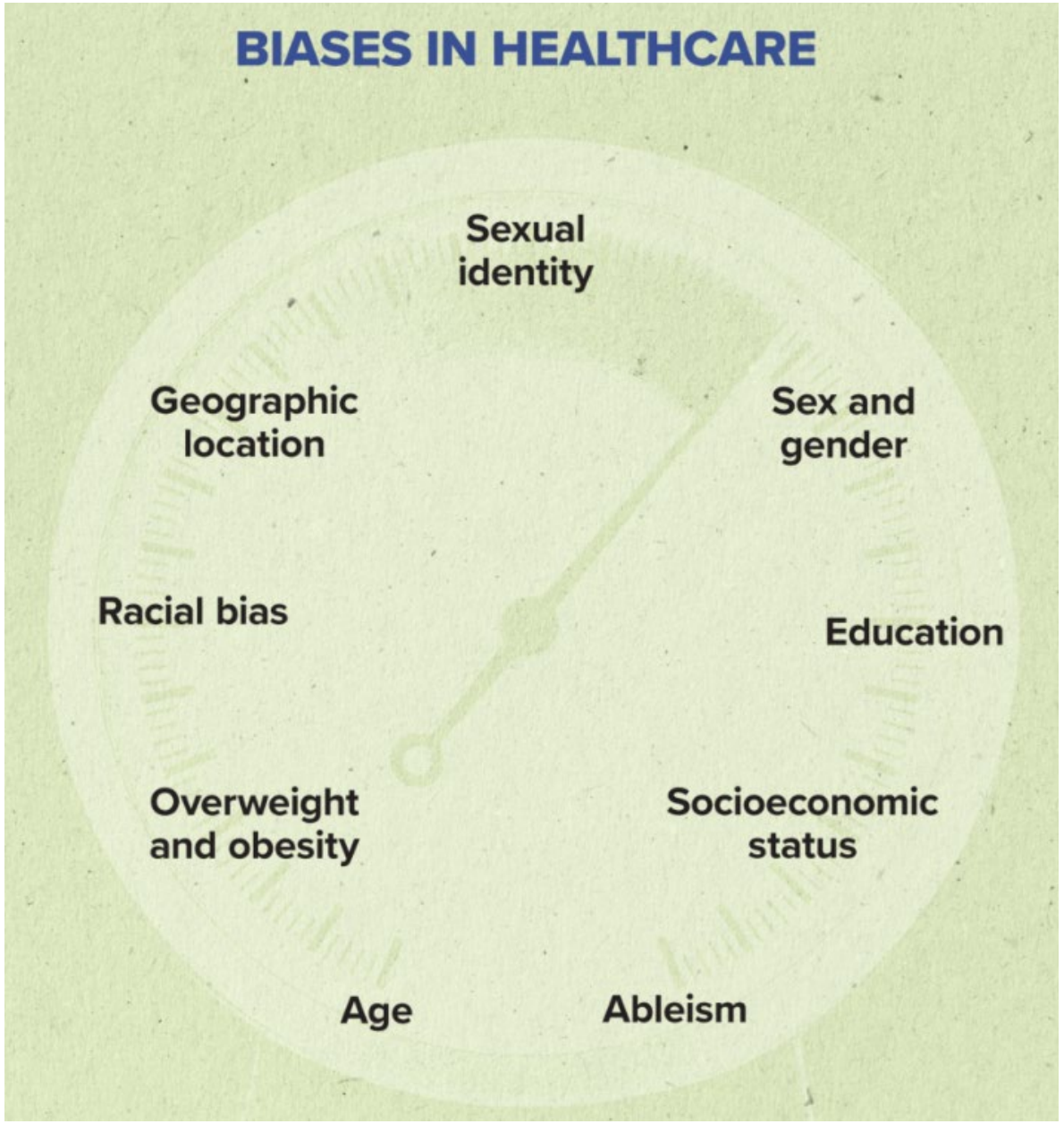
Tannenbaum C et al. Nature 2019



Tannenbaum C et al. Nature 2019

Sources of bias in healthcare, even by experts:

2030



What is being done from a governmental, federal, scientific-community and industry based standpoint for diversity in clinical trials?

THE WHITE HOUSE

NOVEMBER 17, 2023

Launch of White House Initiative on Women's Health Research

GPC › BRIEFING ROOM › BLOG

On November 13, President Biden announced the first-ever White House Initiative on Women's Health Research, an effort led by First Lady Jill Biden and the White House Gender Policy Council.

Aims:

- ✓ Deliver concrete recommendations to advance women's health research
- ✓ Take a targeted, high-impact approach
- ✓ Engage the scientific, private sector, and philanthropic communities

https://www.whitehouse.gov/gpc/briefing-room/2023/11/17/launch-of-white-house-initiative-on-womens-health-research/

Under the 2023 Consolidated Appropriations Act (December 29, 2022)

- lawmakers have instructed FDA to **require diversity plans** for all Phase 3 clinical trials conducted for **drugs and biologics**
- the same **for all devices** and diagnostics that use the 510(k), premarket approval (PMA), de novo, and investigational device exemption (IDE) pathways

https://www.fda.gov/media/170844/download

Diversity, Equity, Inclusion, and Accessibility (DEIA) – targeted by the FDA and others

D **Diversity** means the practice of including the many communities, identities, races, ethnicities, backgrounds, abilities, cultures, and beliefs of the American people, including underserved communities.

E **Equity** means the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment.

I **Inclusion** means the recognition, appreciation, and use of the talents and skills of employees of all backgrounds.

A **Accessibility** means the design, construction, development, and maintenance of facilities, information and communication technology, programs and services so that all people, including people with disabilities, can fully and independently use them. Accessibility includes the provision of accommodations and modifications to ensure equal access to employment and participation in activities for people with disabilities, the reduction or elimination of physical and attitudinal barriers to equitable opportunities, a commitment to ensuring that people with disabilities can independently access every outward-facing and internal activity or electronic space, and the pursuit of best practices such as universal design.

https://www.fda.gov/media/170844/download

FDA diversity plan draft

Diversity Plans to Improve Enrollment of Participants from Underrepresented Racia and Ethnic Populations in Clinical Trials
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

April 2022

Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs
Guidance for Industry

November 2020

https://www.fda.gov/media/157635/download
https://www.fda.gov/media/127712/download

FDA diversity plan draft

Sites and sponsors now know they need to:

- Explain their specific diversity goals
- Justify why they chose those goals based on the disease they're treating
- Describe how they plan to reach those goals

https://www.fda.gov/media/157635/download

FDA workforce DEIA plan

Building on President Biden's Executive Order 14035 "Diversity, Equity, Inclusion, and Accessibility (DEIA) in the Federal Workforce

A change in diversity in clinical trials will only come along with a diverse workforce!

7 objectives aimed at improving DEIA in the FDA and beyond

Objective 1: Increase inclusion of diverse groups by investing in community building and education
Invest in developing agency-wide Employee ce Groups/Affinity Groups (ERG/AGs) with formal support mechanisms to respond to ity priorities through agency actions. Increase the availability of DEIA trai hat celebrate diverse backgrounds and connect employees from a

Objective 2
Enha es
ing performance evaluations, ation, and development opportunities

inue to promote a fair and protective workplace for all
ndardized and centralized processes, procedures, and workflows, including technology- enabled e tracking, and launch a systematic and widespread approach to communicate and educate employees on anti-harassment.

Objective 4: Enhance the collection, analysis, and reporting of demographic information
Drive a set of tactical initiatives to enhance the availability and quality of demographic information available across the employee lifecycle, starting with the recruiting process, and a commitment to analyze available information for actionable insights.

Objective 5: Enhance outreach, recruitment, and retention efforts to increase representation of underrepresented groups
Understand barriers to achieving representation that reflects the civilian workforce within each grade level and establish targeted programs to remove those barriers across various stages of the employee lifecycle.

Objective 6: Improve accessibility across the agency
Assess and bolster the effectiveness of practices used to provide accessibility for FDA employees and prospective employees, including reasonable accommodations, workplace accessibility, and accessibility in information and communication technologies.

Objective 7: Leverage innovation and creativity to meet Center/Office-specific DEIA needs
Provide Center/Office leaders additional flexibility in meeting the DEIA needs of their workforces. Center/Office-specific initiatives that do not align to Strategic Objectives 1-6 will be captured under Objective 7 and the measurement approach will be defined on an initiative-by-initiative basis.

https://www.fda.gov/media/170844/download

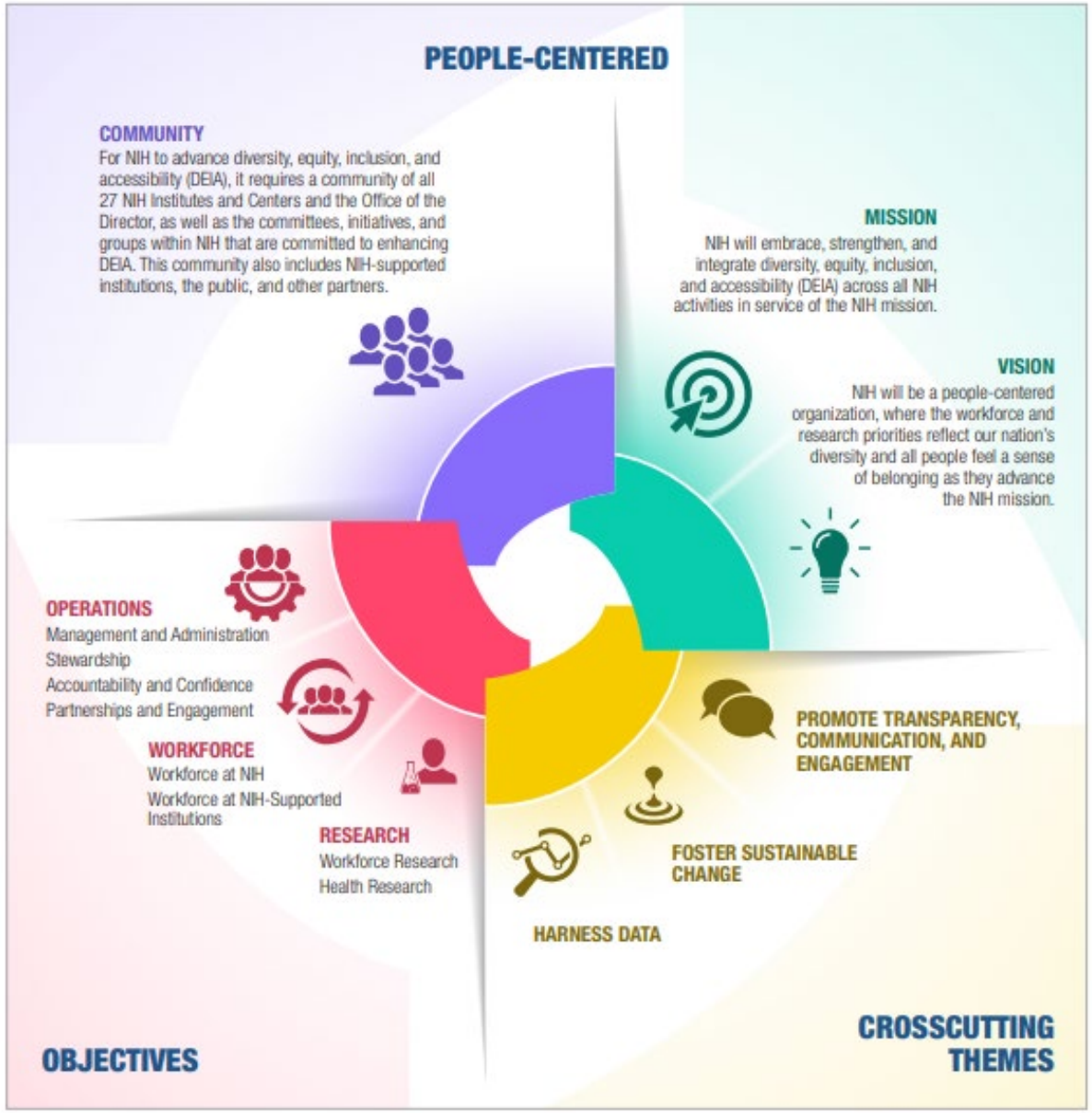
NIH DEIA plan

Three objectives:

- growing and sustaining diversity, equity, inclusion, and accessibility through **structural and cultural change**
- **implementing organizational practices** to center and prioritize diversity, equity, inclusion, and accessibility in the biomedical and behavioral research workforce
- **advancing diversity**, equity, inclusion, and accessibility through **research**

https://www.nih.gov/sites/default/files/about-nih/nih-wide-strategic-plan-deia-fy23-27.pdf

NIH DEIA plan



https://www.nih.gov/sites/default/files/about-nih/nih-wide-strategic-plan-deia-fy23-27.pdf

NIH GRANTS & FUNDING
NIH Central Resource for Grants and Funding Information

Inclusion of Women and Minorities as Participants in Research Involving Human Subjects

Proposals

- All NIH-funded studies **must address plans for the inclusion of women and minorities**
- Any **exclusions** based on **sex/race/ethnicity** must include a **rationale and justification**
- Appropriate **outreach programs** and activities to **recruit** and retain the **proposed study population**
- Valid **analysis of group differences** on the basis of sex/race/ethnicity

Review

- Scientific **Review Groups** will assess each application/proposal being **acceptable** with regard to the **inclusion of racial/ethnic minorities/women**

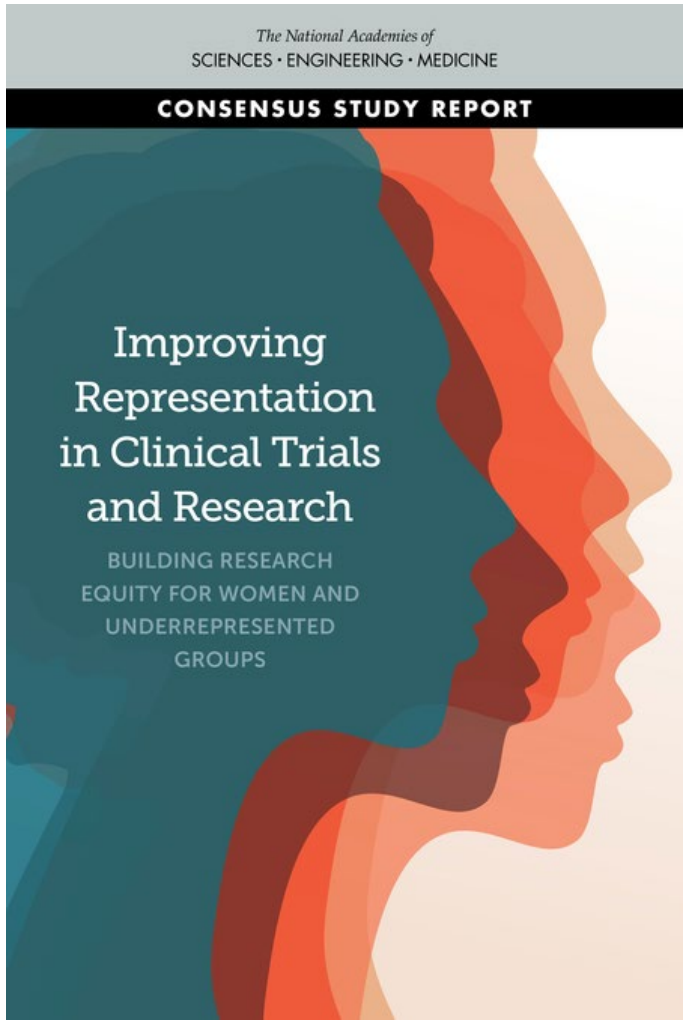
Progress

- annual **report on sex/gender, race/ethnicity** in progress reports

https://grants.nih.gov/policy/inclusion/women-and-minorities.htm

Report from the National Academies of Sciences, Engineering, and Medicine (2022)

Kirsten Bibbins-Domingo et al.



Lack of representation may compound low accrual that causes many trials to fail.

Lack of representation may hinder innovation and new discoveries.

Lack of representation costs hundreds of billions of dollars.

SUMMARY

Lack of representation compromises generalizability of clinical research findings to the whole U.S. population.

Lack of representation may lead to lack of access to effective medical interventions.

Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington, DC: The National Academies Press. 2022

Report from the National Academies of Sciences, Engineering, and Medicine (2022)

SELECTED RECOMMENDATIONS

Reporting and Accountability

- Establish an **intradepartmental task** force on research equity
- **Journal** editors, publishers, and the ICMJE should **require information on the representativeness of trials**
- Require a **detailed recruitment** plan appropriately reflecting the demographics of the disease or condition

Federal Incentives

- **Enforce** existing **accountability measures**
- Expedite coverage decisions for drugs/devices that have been approved based on **representative development programs**
- **Incentivize community providers** to enroll and retain participants in clinical trials by reimbursing

Remuneration

- Ensure that trials provide **adequate compensation for research participants**
- Federal regulatory agencies should develop explicit guidance to direct local IRBs on **equitable compensation** to research participants and their caregivers.

Education, Workforce, and Partnerships

- Ensure a **diverse and inclusive workforce**, especially in leadership positions
- Leaders and faculty of academic medical centers should recognize research and professional efforts to advance **community engaged scholarship**
- Substantially **invest in community research infrastructure**

Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington, DC: The National Academies Press. 2022

Reaction of the industry

MERCK

Diversity and equity in our clinical trial research

Pfizer

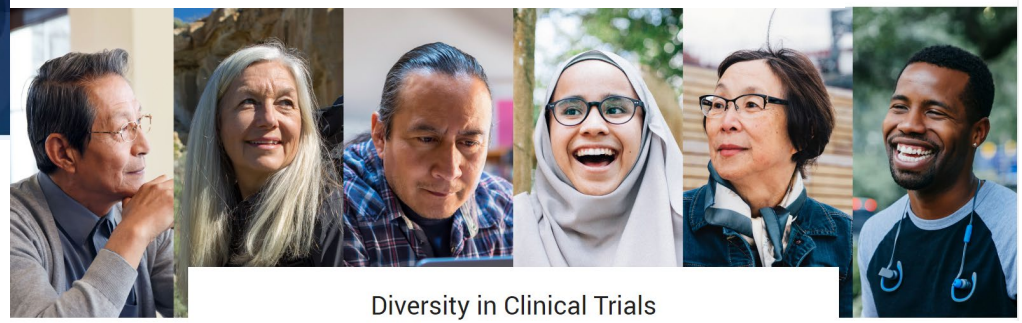
Diversity in Our Clinical

AMGEN

Home > Science > Clinical Trials > Clinical Trial Diversity and Representation

Clinical Trials

Lilly



Diversity in Clinical Trials

NOVARTIS

Diversity in Clinical Trials

BAYER | CLINICAL TRIALS EXPLORER

Enhancing Diversity in Clinical Trials

At Bayer, we know there is strength in diversity - a value which is reflected in our commitment to our employees and the population we serve. Through our vision of "Health for all, hunger for none," we are committed to the goal of inclusive clinical trials that represent the diversity required to address the needs of all patients. To accomplish this, we are working with clinicians, research scientists, vendors, health authorities, ethics committees, and partners in patient engagement to ensure that our purpose of "Science for a Better Life" touches every life, regardless of race, ethnicity, sex/gender, age, or any other characteristic that may present a barrier to clinical trial participation.

A multitude of diversity plans exist across the industry, implementation is however lacking!

Conclusions

- There is **not much change in inclusion of women minority populations in CVD trials** over recent years
- **Increasing diversity among trial participants must be a top priority** in order to address health disparities and allow for optimal diagnosis and management of CVD in all
- **Increasing diversity in trial leadership** is one of the most important strategies **to increase diversity among RCT participants**
- Further efforts are urgently needed to **increase diversity in the cardiology workforce**, which will improve clinical trial diversity and cardiovascular health for all
- Approaches from the **whole scientific community** to tackle the inequality in workforce, trial leadership and trial participants have to be developed

THANK YOU FOR YOUR ATTENTION !

Mount Sinai Fuster Heart Hospital

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