



# Inclusion and Diversity in Clinical Trials: Actionable Steps to Drive Lasting Change

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**DukeHealth**

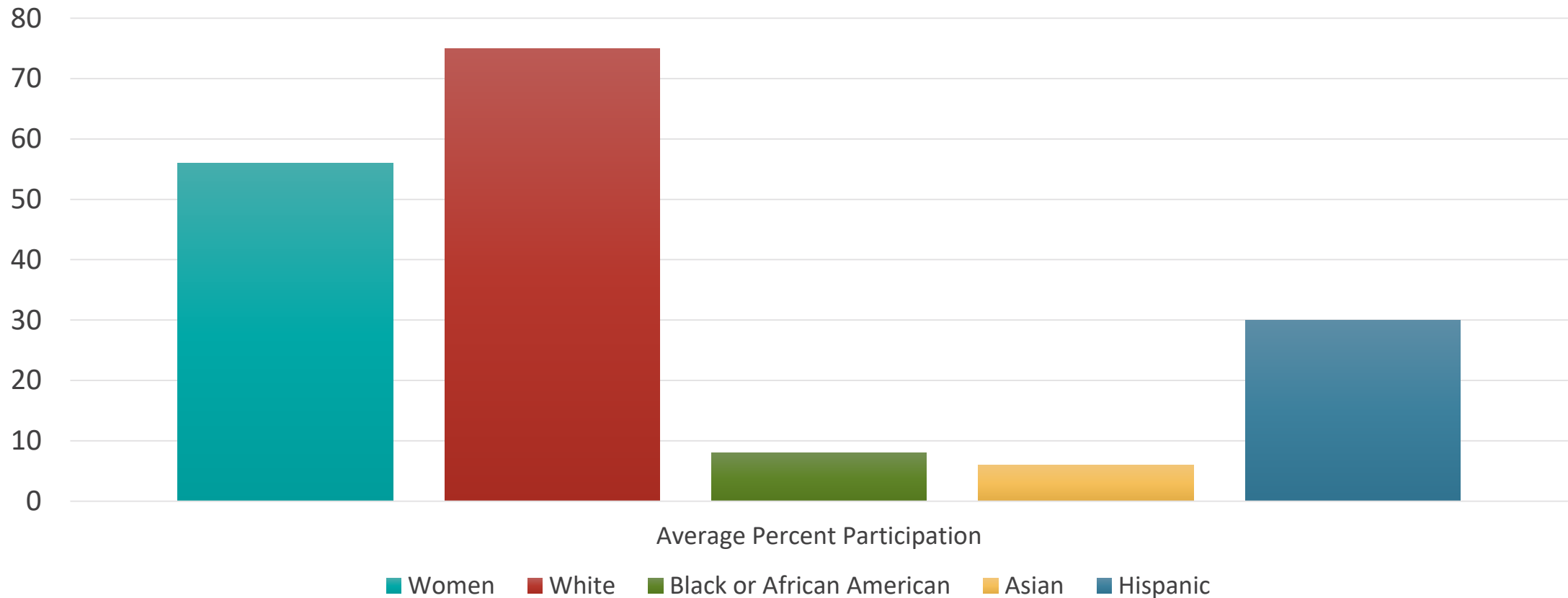


# Outline

- State of Diversity in Clinical Trials in the U.S.
- Diversity in Clinical Trials as a National Priority
- DCRI Think Tank Approach
- DCRI Think Tank Results
- Summary and Discussion

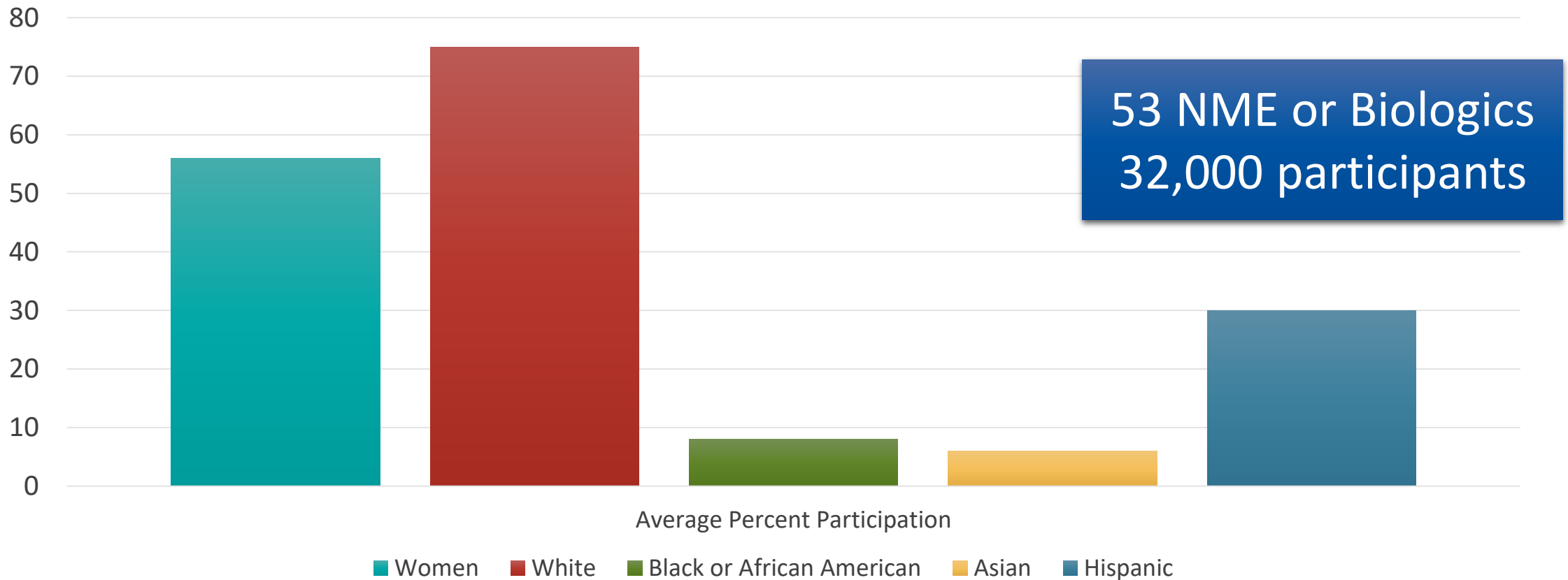


# Participation in Clinical Trials of New Molecular Entities and Therapeutic Biologics by Race (2020)



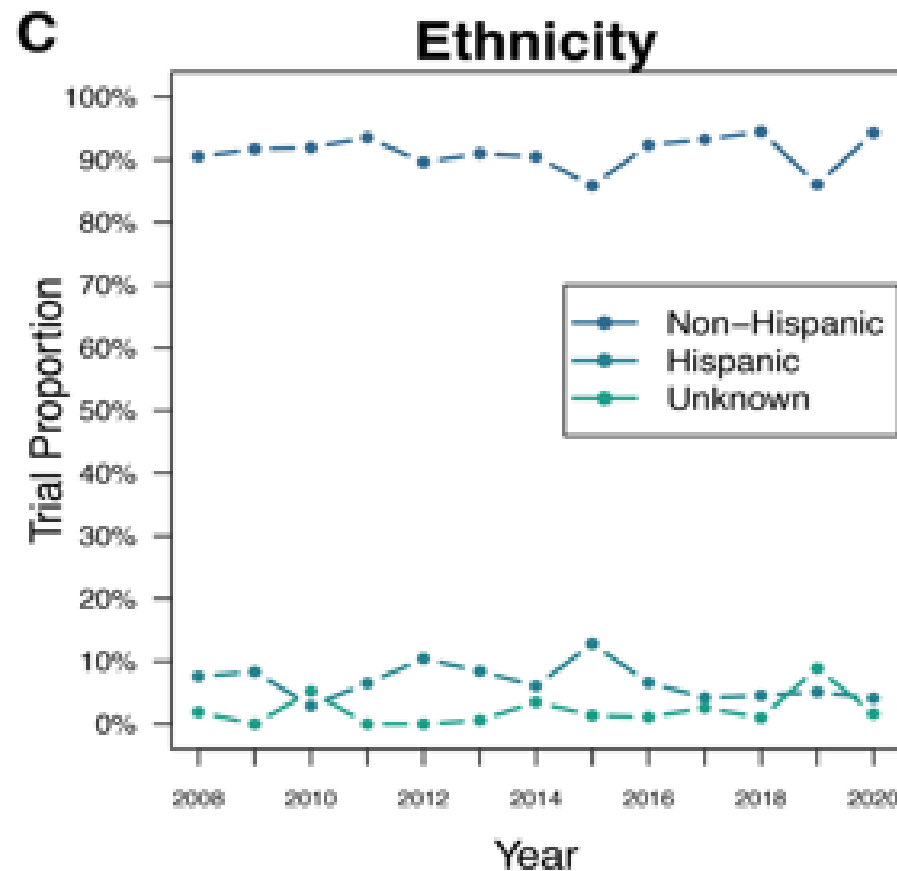
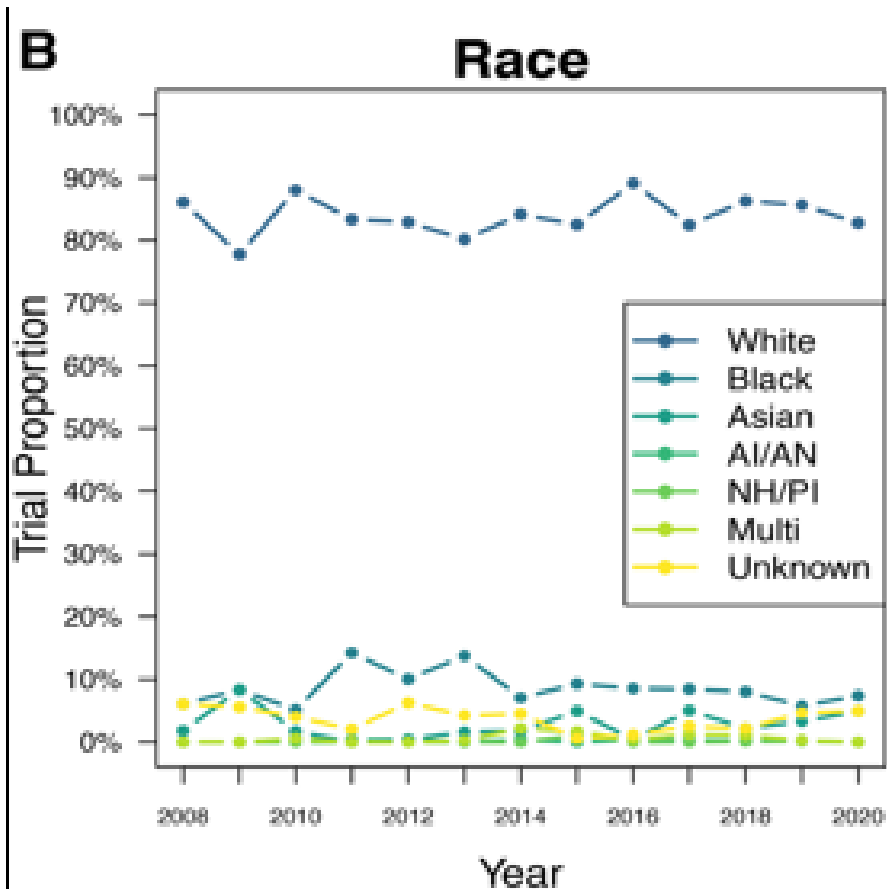


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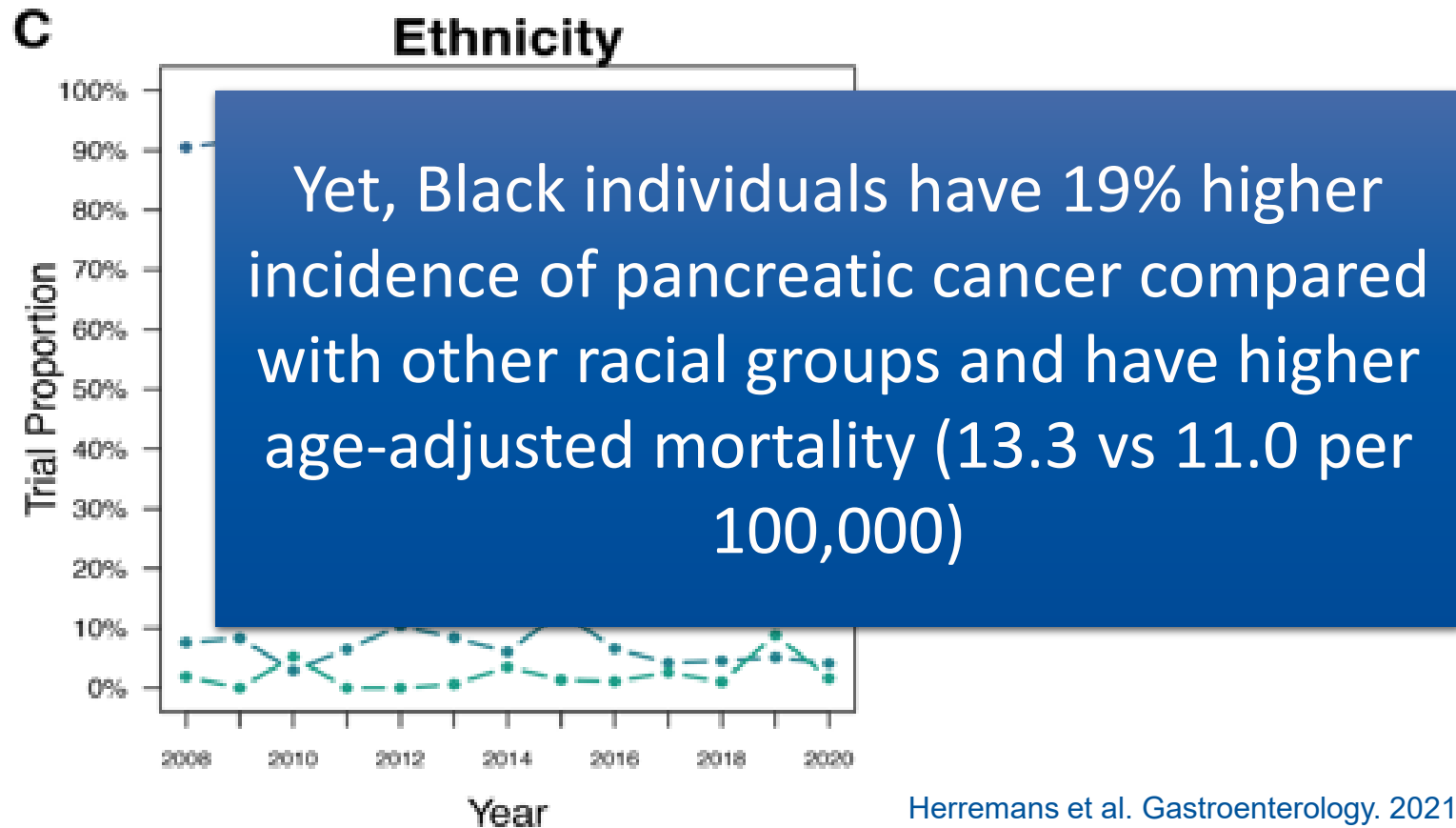
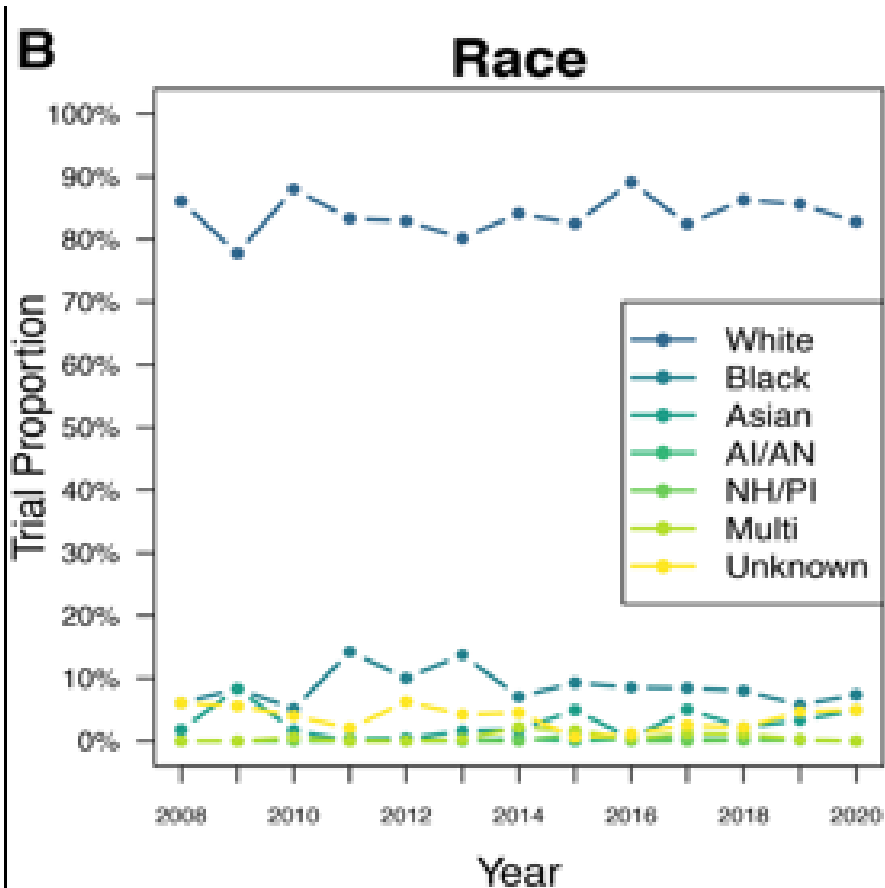


# Racial and Ethnic Minorities Underrepresented in Pancreatic Cancer Clinical Trials





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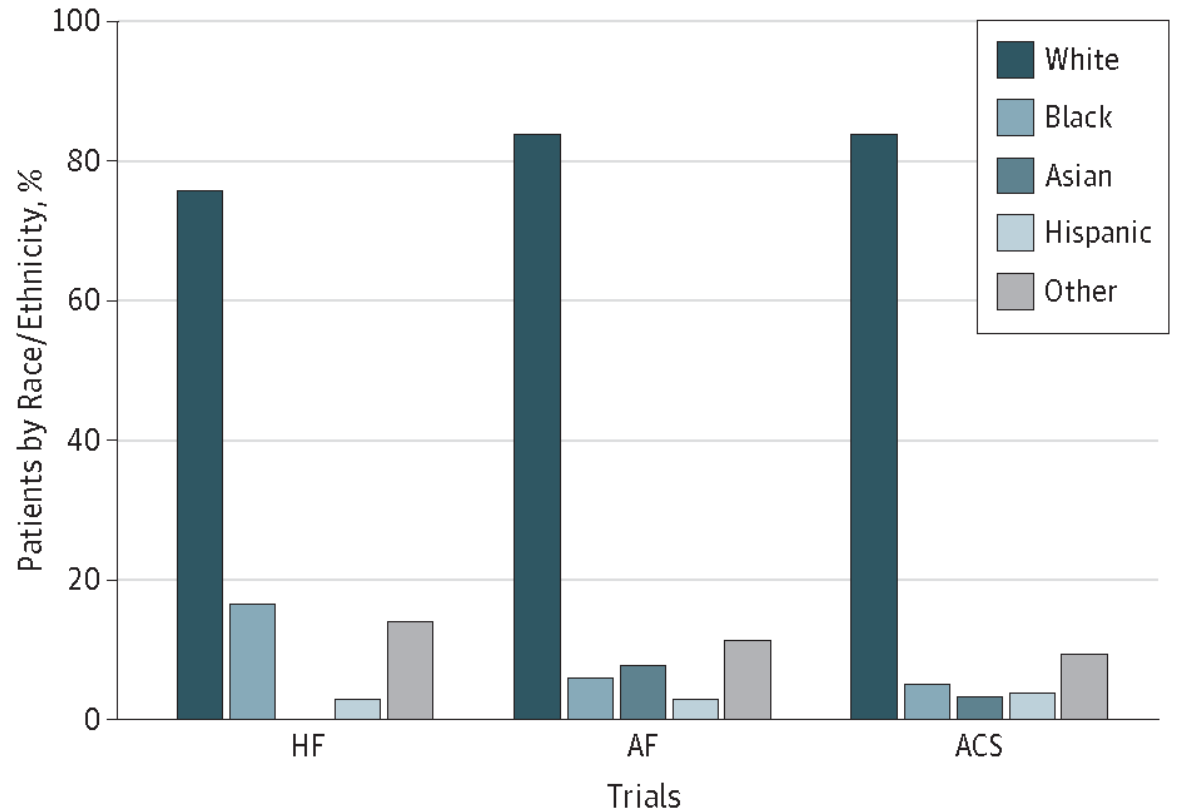
# Underrepresentation of Older Adults in Cardiovascular Clinical Trials Despite NIH Inclusion Policy

Table. Characteristics of US Cardiovascular Disease Trials Before and After Implementation of the Inclusion Across the Lifespan Policy

Characteristic	No. (%)		P value
	Prepolicy (n = 47)	Postpolicy (n = 50)	
Age limit listed	14 (30)	16 (32)	.81
Upper age limit, y			
≤70	1 (2)	1 (2)	>.99
≤75	3 (6)	3 (6)	>.99
≤80	5 (11)	9 (18)	.30
≤85	8 (17)	11 (22)	.54
≥90	6 (13)	5 (10)	.67
No age limit	33 (70)	34 (68)	.81



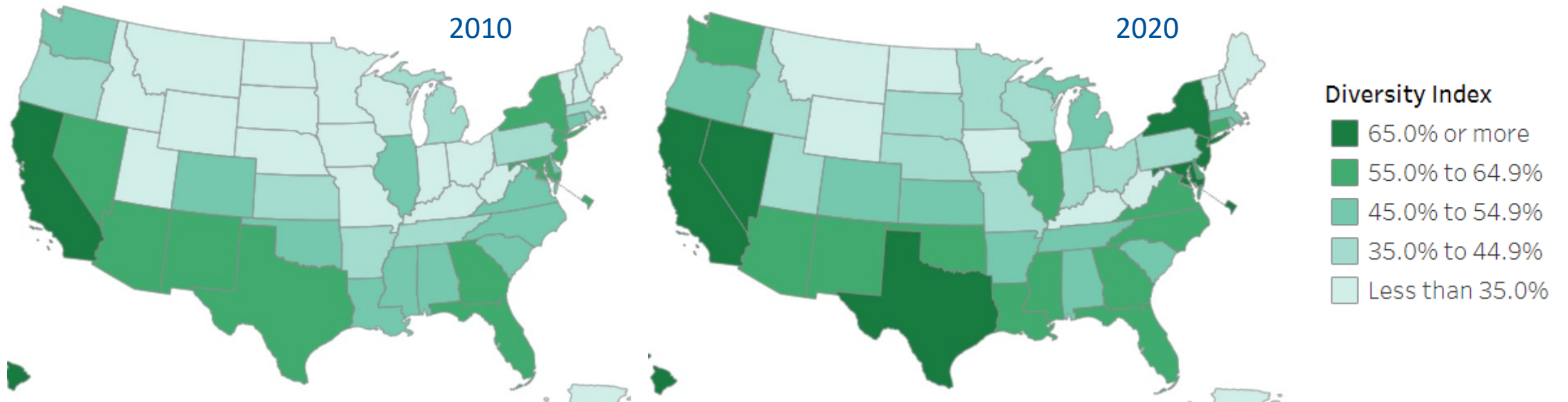
# Underrepresentation of Women and Racial Minorities Impacting Cardiovascular Guidelines







# Increasing Racial Diversity, US Census 2010-2020



Diversity Index: Likelihood that two people chosen at random from population will be of different races



# Shifting Demographics of the United States

Figure 1.

## Projections of the Older Adult Population: 2020 to 2060

By 2060, nearly one in four Americans is projected to be an older adult.

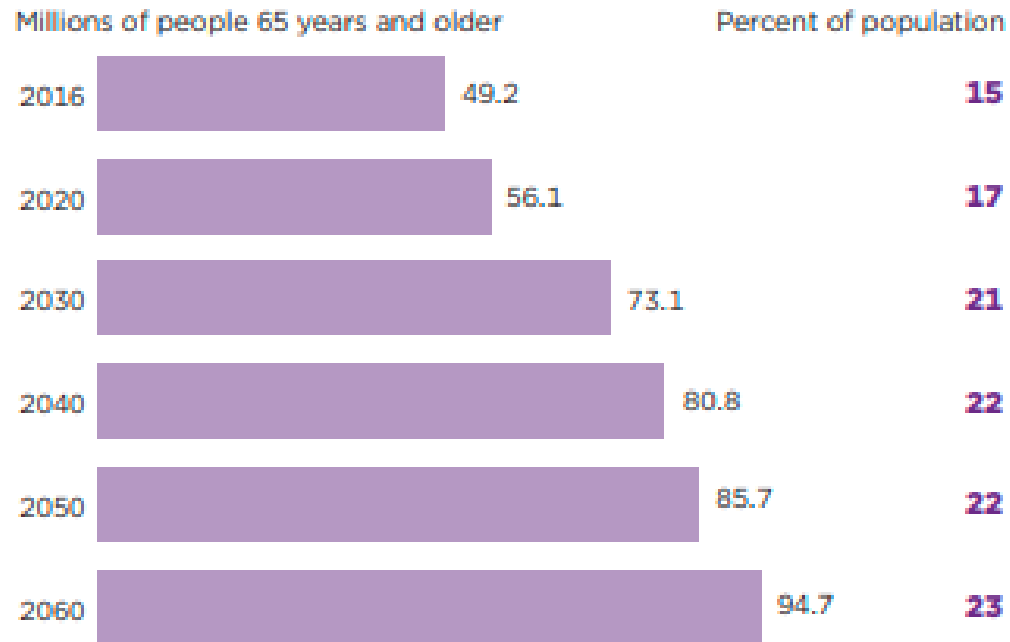
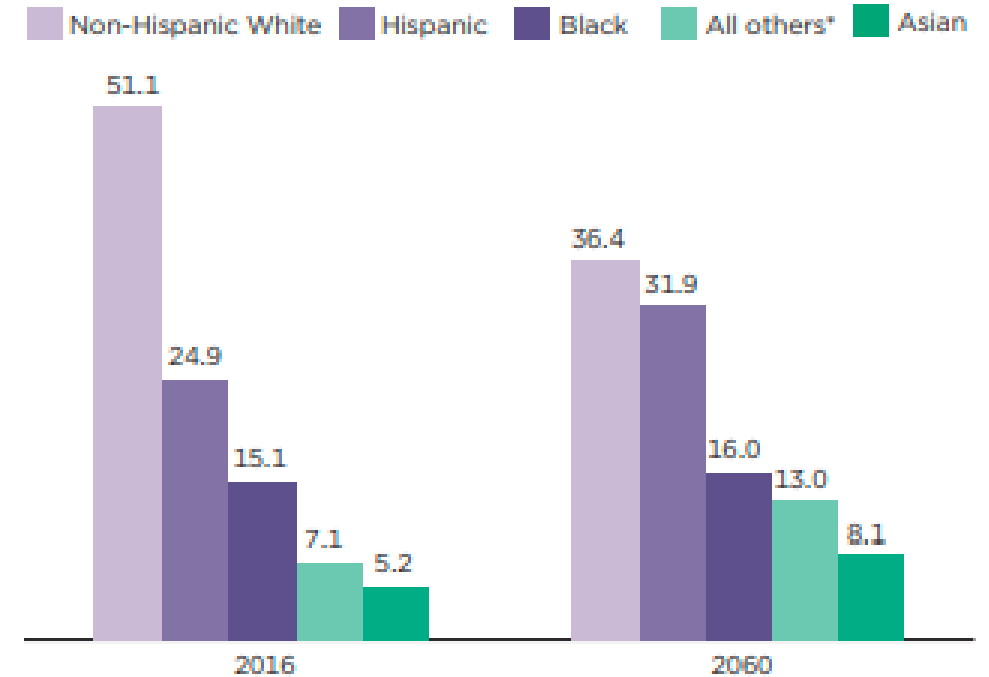


Figure 3.

## Racial and Ethnic Composition of Children Under Age 18

The share of children who are non-Hispanic White is projected to fall from one-half to about one-third by 2060. (In percent)





## National Priority: Regulatory perspective

- Published 2020
- Recommendations for trial sponsors on increasing enrollment of under-represented groups
- Improve accessibility
- Broaden eligibility criteria

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

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)

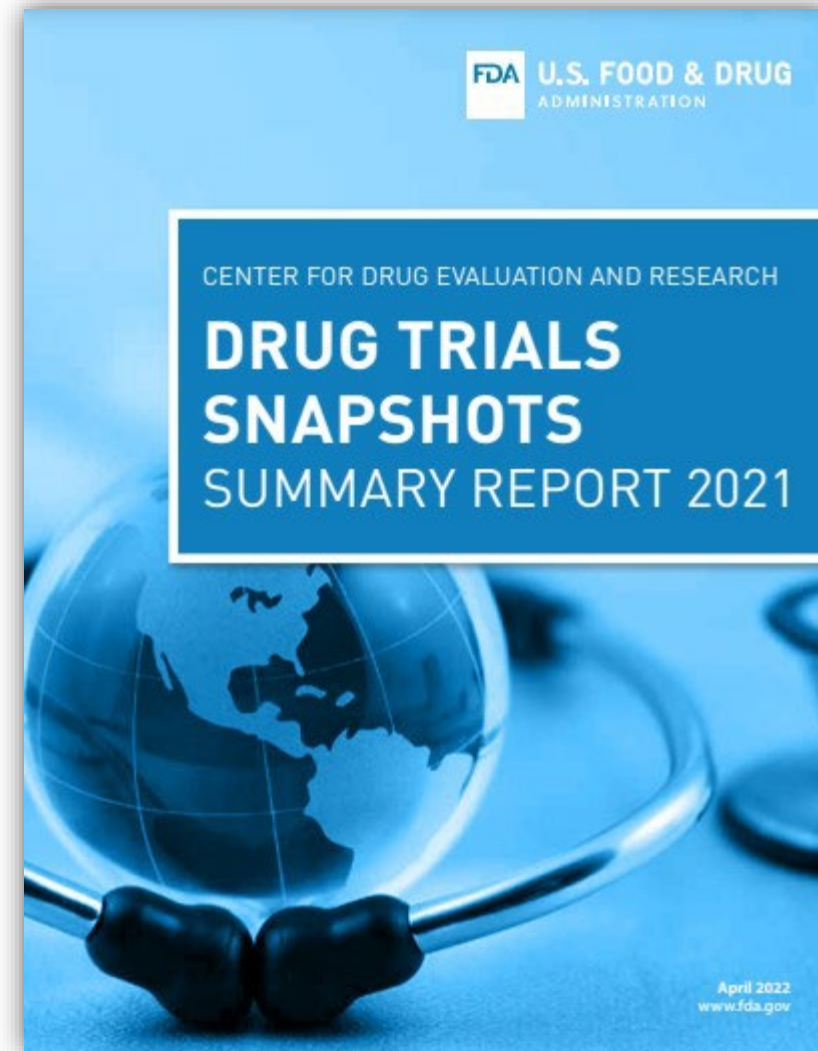
November 2020  
Clinical/Medical

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# National Priority: Regulatory perspective

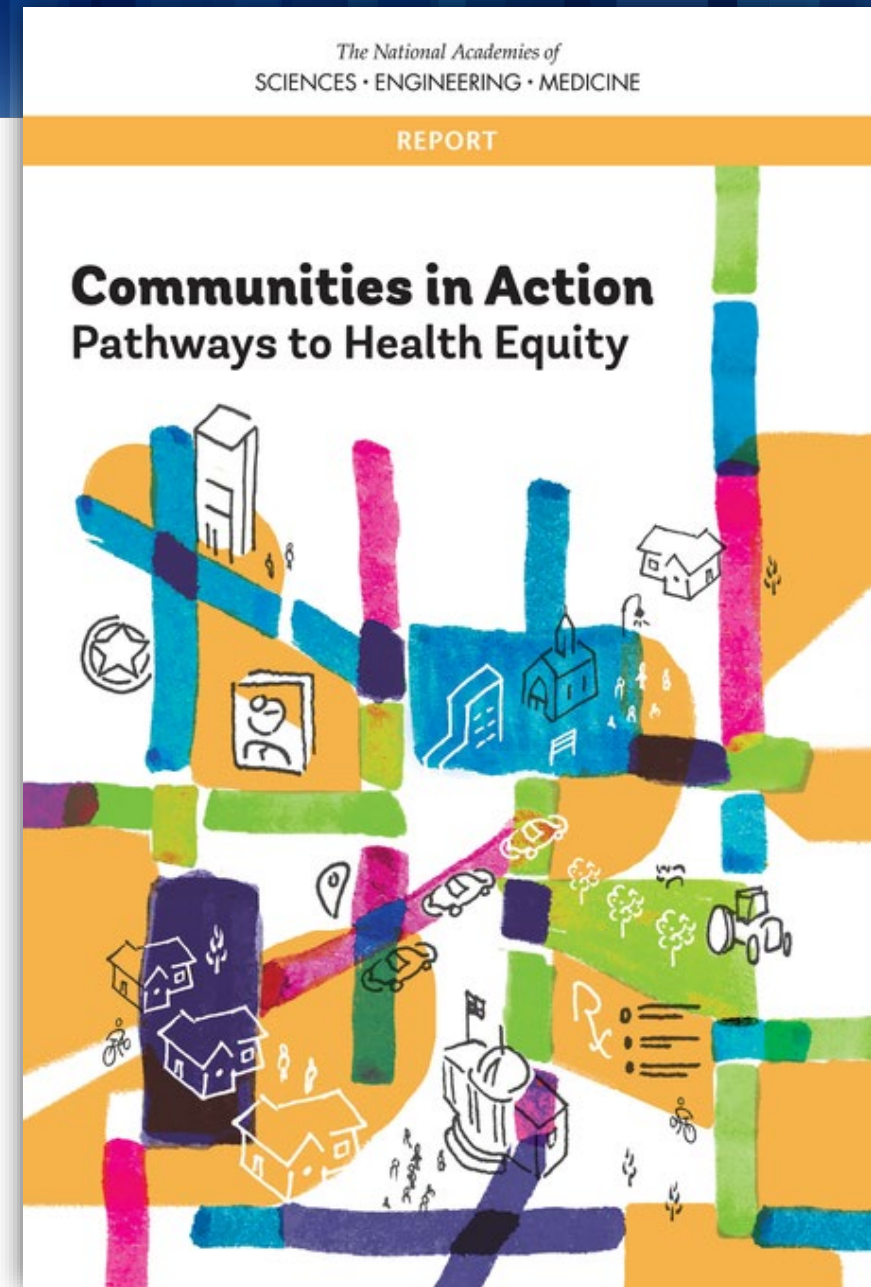
- Demographic inclusion data of clinical trials for approved New Molecular Entities and original biologics





# National Priority: Funding Agencies

- Published by National Academies of Sciences
- Seeks to delineate the causes of and the solutions to health inequities in the United States
- Offers community based solutions







# National Priority: Industry

- Many companies working towards improving diversity in clinical trials
- Merck participating one such initiative in collaboration with Novartis

**Global race distribution for clinical trials**

Race	Percentage
White	76%
Asian	11%
Black or African American	7%
Other	5%
American Indian or Alaska Native	1%

**It's for Us**

Diverse representation of minorities in clinical trials is essential to help researchers better understand patterns of difference in health and sickness based on various racial, ethnic, and geographic backgrounds.

**Play an active role in your personal healthcare by participating in clinical trials!**

**A few reasons why you or your loved ones should consider participating:**

- 1 Receive medical care from professionals knowledgeable of your condition.
- 2 Learn more about your health condition.
- 3 Participation is voluntary, you can leave the clinical trial at any time.

**MERCK**

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Learn more about clinical trials and speak to your health care provider today.

To find a trial in your area visit:  
[www.merckclinicaltrials.com/](http://www.merckclinicaltrials.com/)



# National Institute of Health: Community Engagement Alliance (CEAL)

“To provide trustworthy, science-based information through active community engagement and outreach to the people hardest-hit by the COVID-19 pandemic, with the goal of building long-lasting partnerships as well as improving diversity and inclusion in our research response to COVID-19”



# National Institute of Health: Community Engagement Alliance (CEAL)



**How CEAL Teams Work**

The image shows a teal-colored map of the United States with several circular icons of diverse people placed across different regions, representing the nationwide reach of CEAL teams.

**Areas of Focus**

The diagram consists of three circular icons connected by lines: a computer monitor with a red virus icon on the screen, a syringe, and a red virus particle, representing the focus on digital health, clinical interventions, and infectious diseases.

**COVID-19 Research Networks**

The diagram shows a central circular icon containing a microscope and a virus particle, surrounded by six circular icons of healthcare workers (nurses, doctors, and researchers) connected by dashed lines, representing a collaborative research network.





# DCRI Think Tank

- Organized and sponsored by the Duke Clinical Research Institute
- Held virtually April 28-29, 2021
- Attendees selected by Think Tank faculty and staff of the DCRI
- Representatives from each organization had opportunity to extend invitation to others

**DCRI THINK TANKS**  
FROM INSIGHT TO ACTION



# DCRI Think Tank: Methods

- Representatives from:
  - U.S. Food and Drug Administration
  - National Institutes of Health
  - Academic institutions/Clinical investigators
  - Pharmaceutical and device companies
  - Community-based organizations
  - Data analytics companies
  - Patient advocacy groups



# DCRI Think Tank: Key Questions

- What are the best practices for participant engagement with underrepresented populations during study design, recruitment, and trial execution?
- How can we create mutual benefit and value that drives sustained engagement and retention of underrepresented populations?
- How can the use of digital approaches increase diversity and retention, and how can we ensure that we use technologies to eliminate, rather than increase, disparities?
- What are the characteristics and strategies of sites and teams that consistently achieve inclusive enrollment?
- What concrete steps can be taken to develop a more inclusive, diverse network of trial investigators and leaders?



# DCRI Think Tank: Methods

- Clinical trials considered broadly according to NIH definition
- Following FDA Center for Drug Evaluation and Research approach, Think Tank focused on gaps in representation of racial and ethnic minorities, women, and older adults
- In accordance with the AMA guidance, racial and ethnic groups discussed reflect race and ethnicity as a social construct, influenced by cultural, economic, and political forces with little biologic or genetic basis



Contents lists available at [ScienceDirect](#)

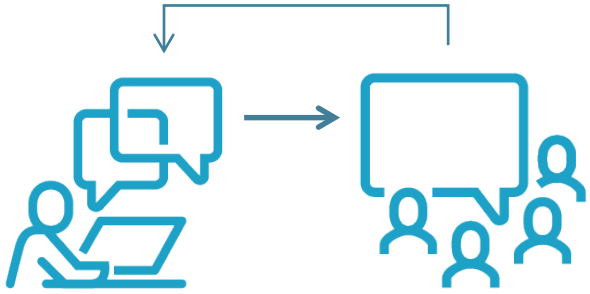
## Contemporary Clinical Trials

journal homepage: [www.elsevier.com/locate/conclintrial](http://www.elsevier.com/locate/conclintrial)

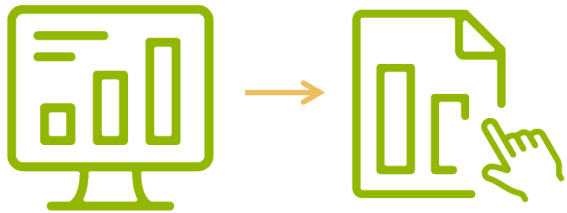


### Inclusion and diversity in clinical trials: Actionable steps to drive lasting change

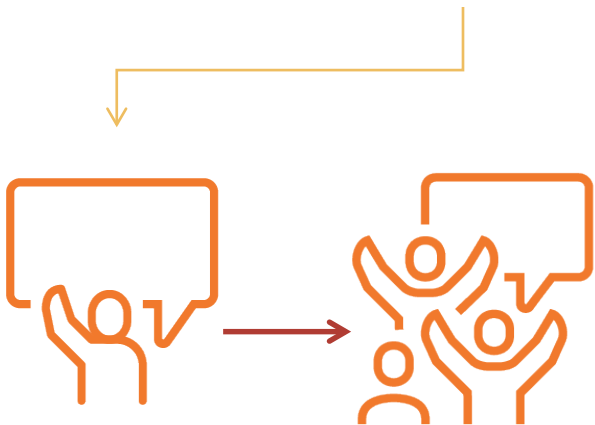
Michelle D. Kelsey<sup>a,b</sup>, Bray Patrick-Lake<sup>c</sup>, Raolat Abdulai<sup>d</sup>, Uli C. Broedl<sup>e</sup>, Adam Brown<sup>f</sup>, Elizabeth Cohn<sup>g</sup>, Lesley H. Curtis<sup>b,h</sup>, Chris Komelasky<sup>i</sup>, Michael Mbagwu<sup>j</sup>, George A. Mensah<sup>k</sup>, Robert J. Mentz<sup>a,b</sup>, Amesika Nyaku<sup>l</sup>, Stephanie O. Omokaro<sup>m</sup>, Judy Sowards<sup>n</sup>, Kendal Whitlock<sup>e</sup>, Xinzhi Zhang<sup>o</sup>, Gerald S. Bloomfield<sup>a,b,\*</sup>



**Build Partnerships with Participants and Communities.**



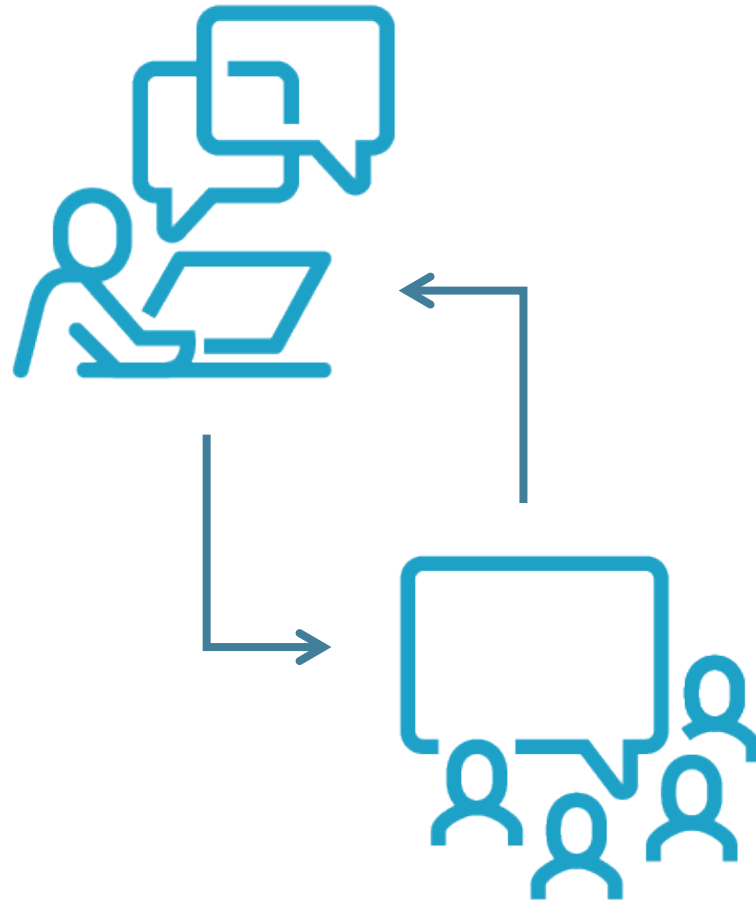
**Improve Accessibility of Clinical Trials.**



**Improve Representation Among Clinical Investigators.**



# Build Partnerships with Participants and Communities

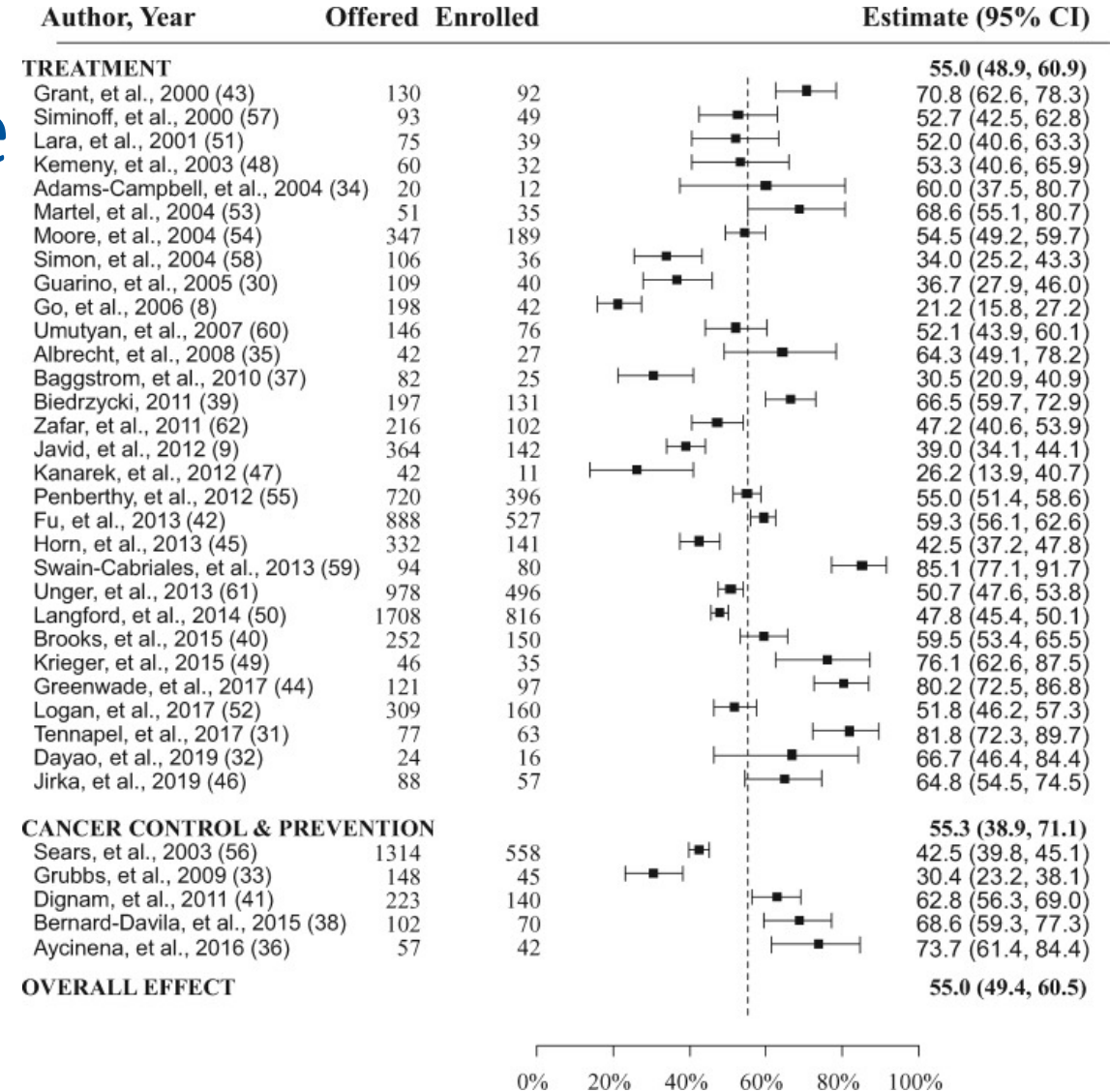






# When Offered to Participate

- Among 35 studies, N=9759 patients offered clinical trial participation
- 55% (95% CI: 49.4-60.5%) of those approached agreed to enroll
- Black patients: 58.5% (95% CI: 46.8%-69.7%)
- White patients: 55.1% (95% CI: 44.3%-65.6%)



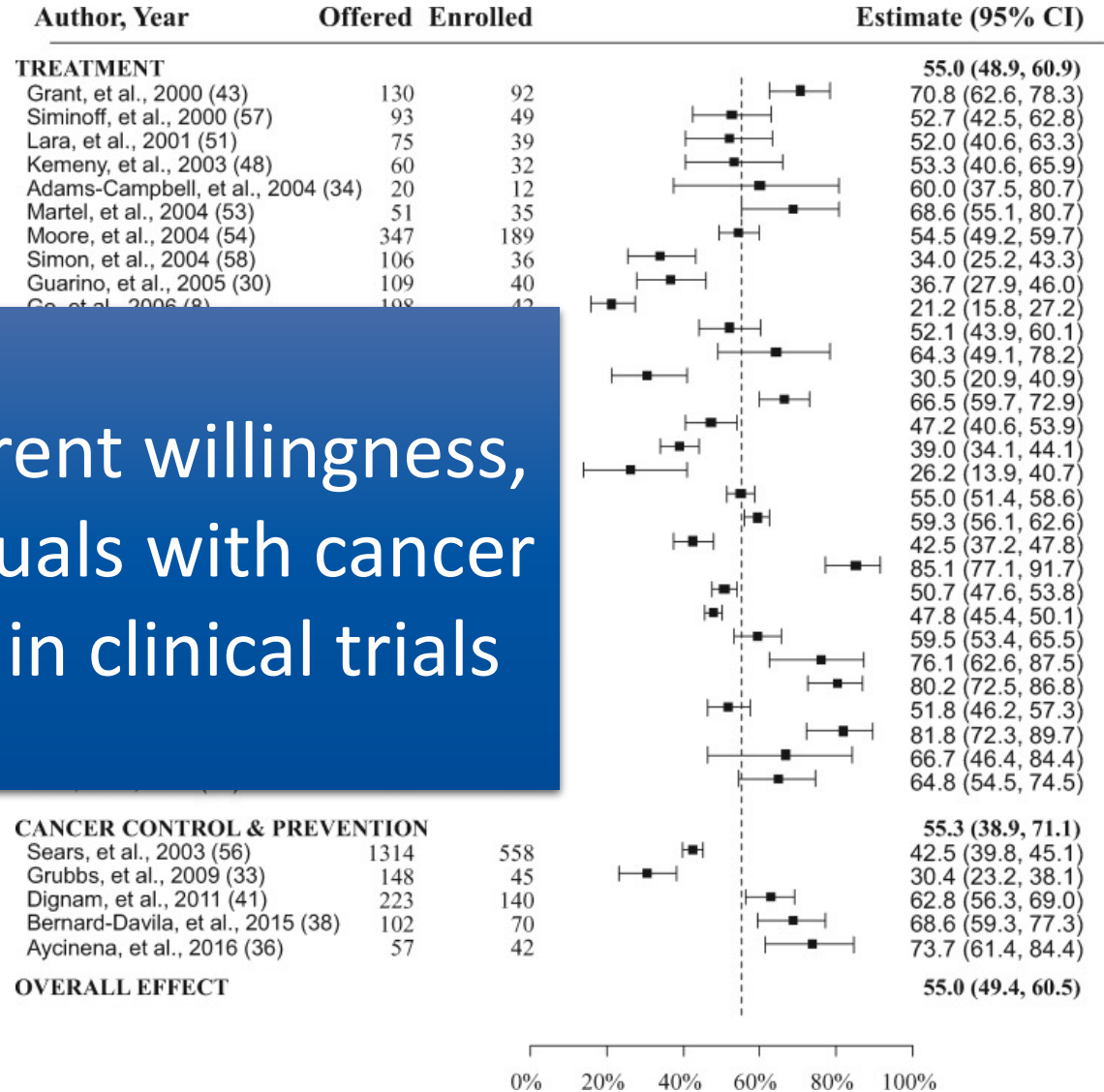




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Despite this apparent willingness, only 8% of individuals with cancer in the U.S. enroll in clinical trials





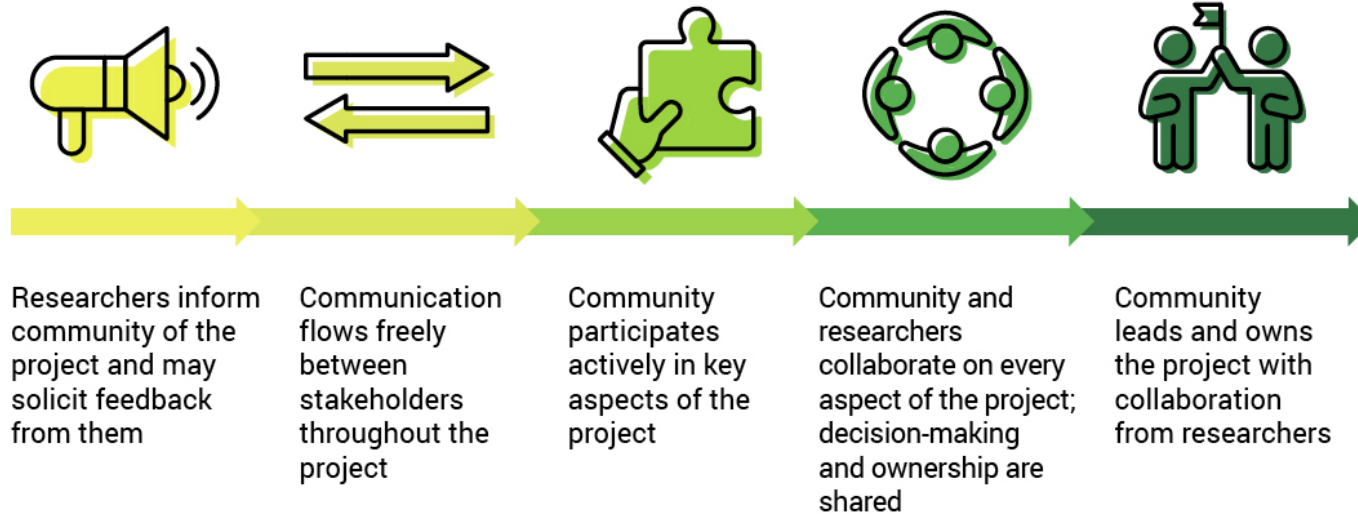
# Build Partnerships with Participants and Communities

- Community engagement particularly effective for recruitment of racial and ethnic minority groups
- In systematic reviews, community involvement and partnership with community-based organizations *universally* cited as key to success.
- Beneficial for participant retention (65% retention rate across community-base participatory research studies).



# Build Partnerships with Participants and Communities

## Level of community engagement





# Build Partnerships with Participants and Communities

- What is the reputation and involvement of my work in the community?
- Does the outcome of this study benefit health in the community?
- When did we ask for input? When did you talk to the community, at the start or just for engagement/recruitment?
- When and how will I return results?
- Are you a trusted and generous community resource?
- Can you link the community to services where needed?



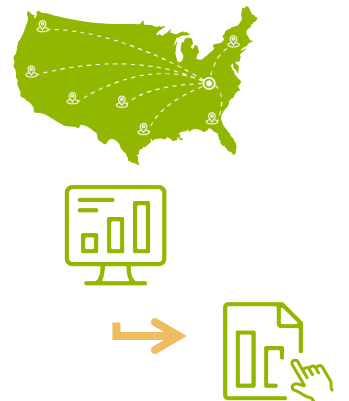
# Improve Accessibility of Clinical Trials





# Improve Accessibility of Site Networks and Research Infrastructure

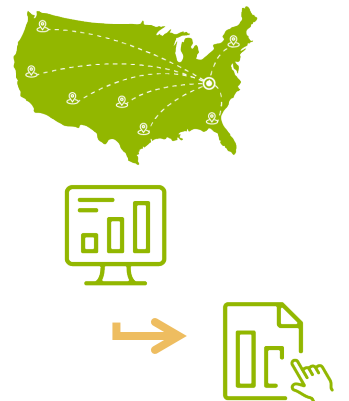
- Decentralized clinical trials to reduce geographic barriers
- Leverage community infrastructure already in place
- Use of digital tools





# Improve Accessibility of Site Networks and Research Infrastructure

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# Accessibility of Clinical Trials

Table. Proportion of US Patients With Metastatic Disease Across Categories of Driving Time to the Nearest Clinical Trial Site<sup>a</sup>

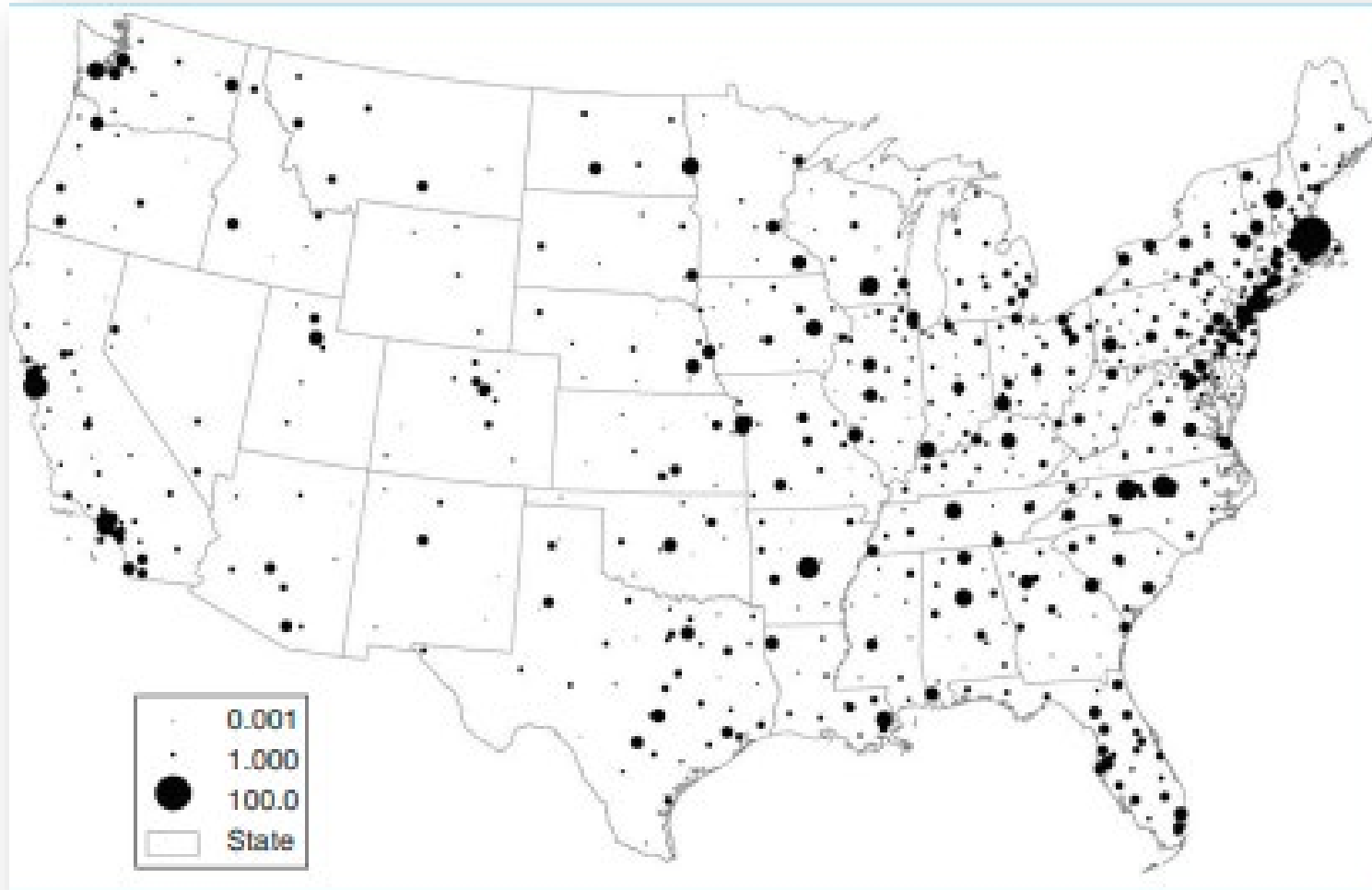
Cancer Type	Patients, No.	Population, %					
		<30 min	30 min to <1 h	1 h to <2 h	2 h to <3 h	3 h to <4 h	>4 h
Breast	40 981	24.9	29.3	27.8	11.6	4.5	1.7
Prostate	28 699	23.4	26.4	33.9	11.5	3.5	1.3
Colorectal	50 641	21.1	26.7	33.6	13.3	2.9	2.4
Non-small cell lung	157 183	28.1	33.5	28.7	8.1	1.2	0.4

<sup>a</sup> Number and geographic distribution of patients with metastatic disease approximated by using cancer-specific mortality data from [wonder.cdc.gov](http://wonder.cdc.gov).



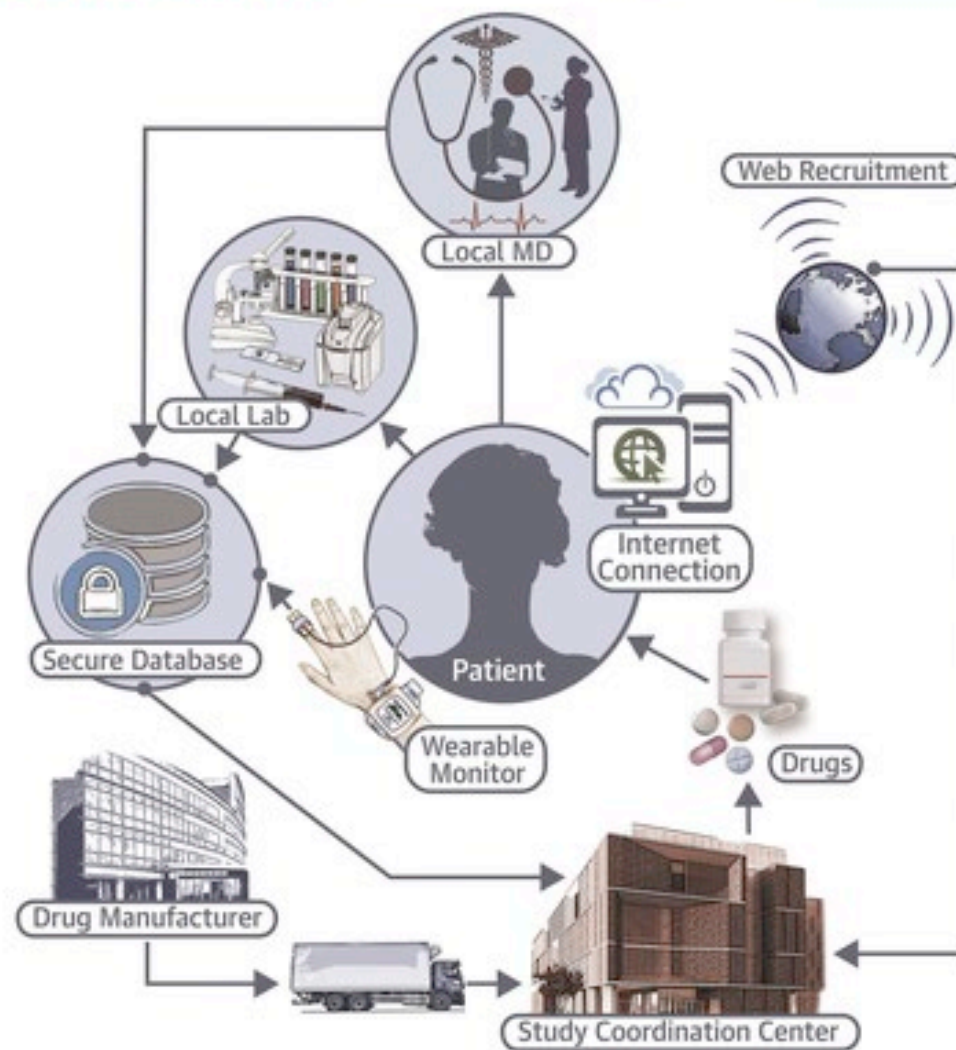


# Number of Clinical Trial Sites per 10,000 persons





## CENTRAL ILLUSTRATION Decentralized Clinical Trials

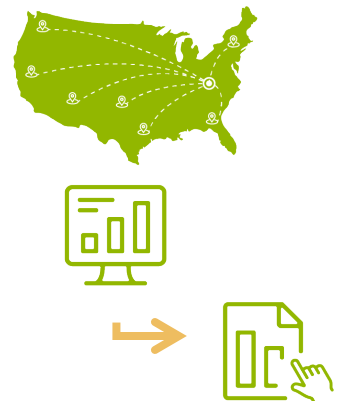


Van Norman, G.A. J Am Coll Cardiol Basic Trans Science. 2021;6:384-387.



# Improve Accessibility of Site Networks and Research Infrastructure

- Decentralized clinical trials to reduce geographic barriers
- **Use of Digital Tools**
- Leverage community infrastructure already in place





# Digital Health Technology

- Identified by FDA as key strategy to enhance diversity in clinical trial.
- Digital Tools: electronic sensors or devices that detect and measure a physical characteristic and transmit to a study database.
- Increase engagement
- Decrease participant burden



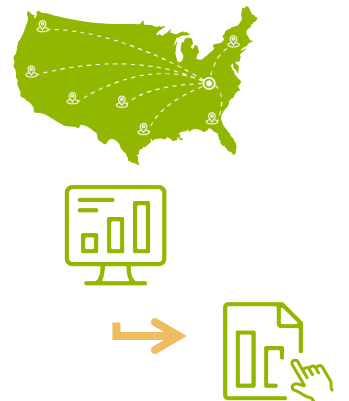
# Digital Health Technology: Use with Caution

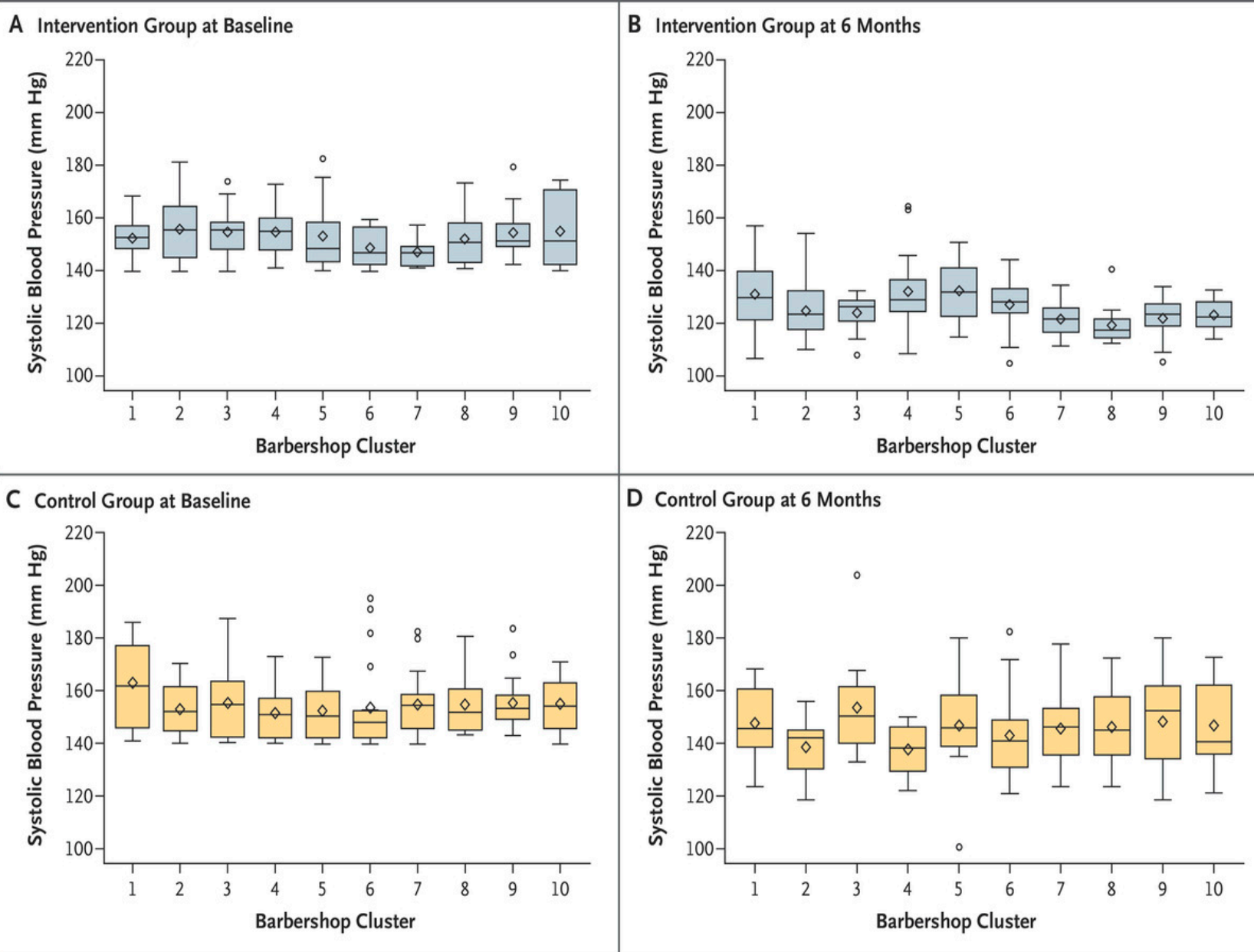
- 97% of Americans own cellphone, 85% own smartphone
- Internet access limited in rural areas
- Private space to discuss medical information
- Digital literacy



# Improve Accessibility of Site Networks and Research Infrastructure

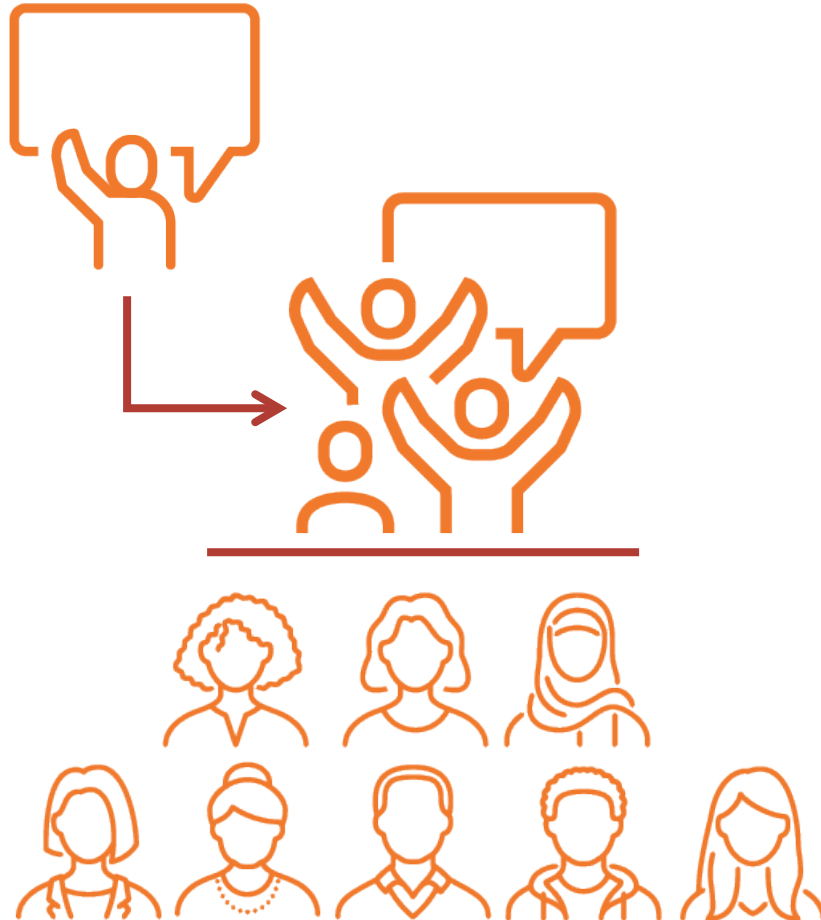
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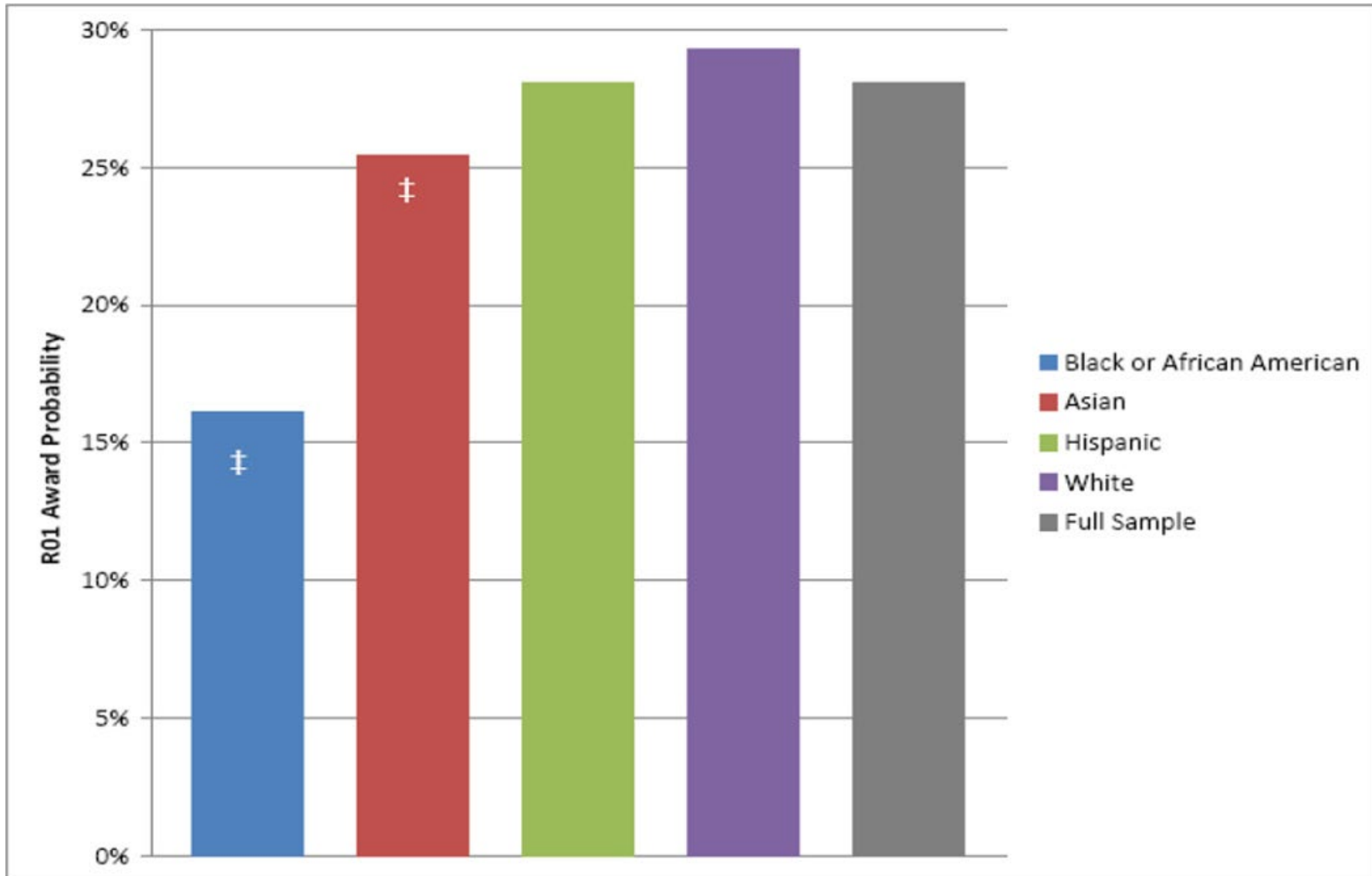




# Improve Representation Among Clinical Investigators

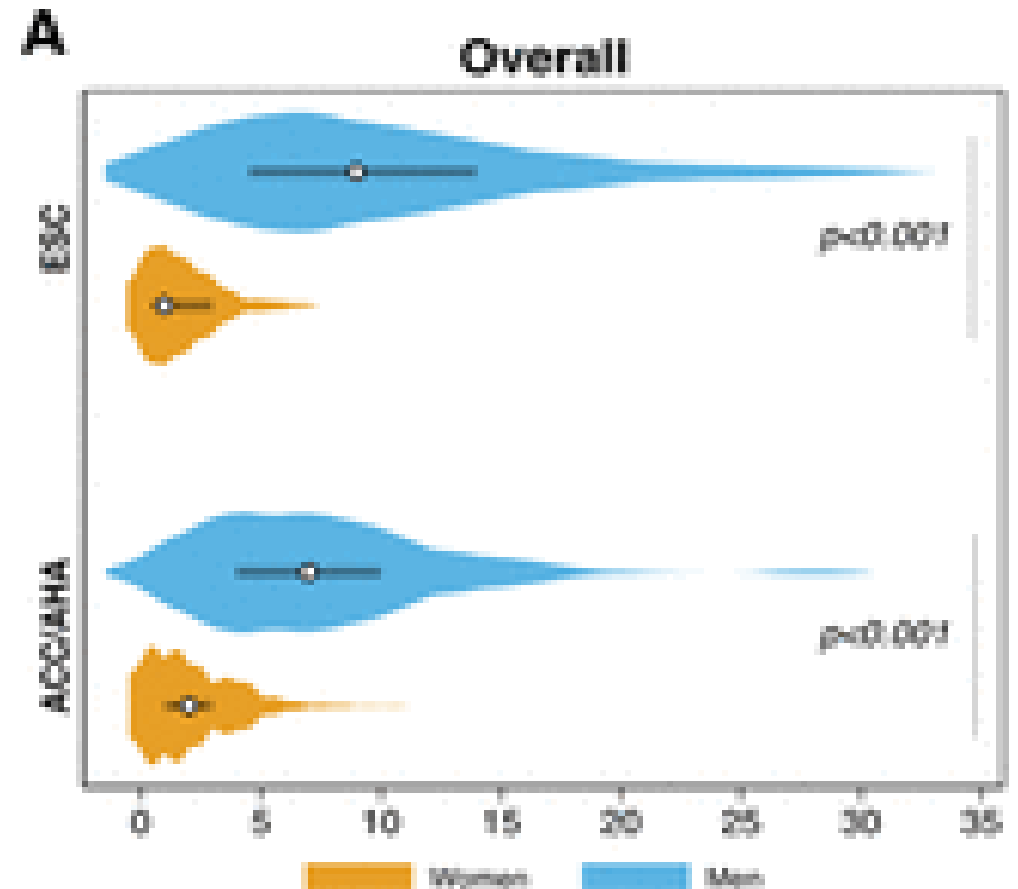
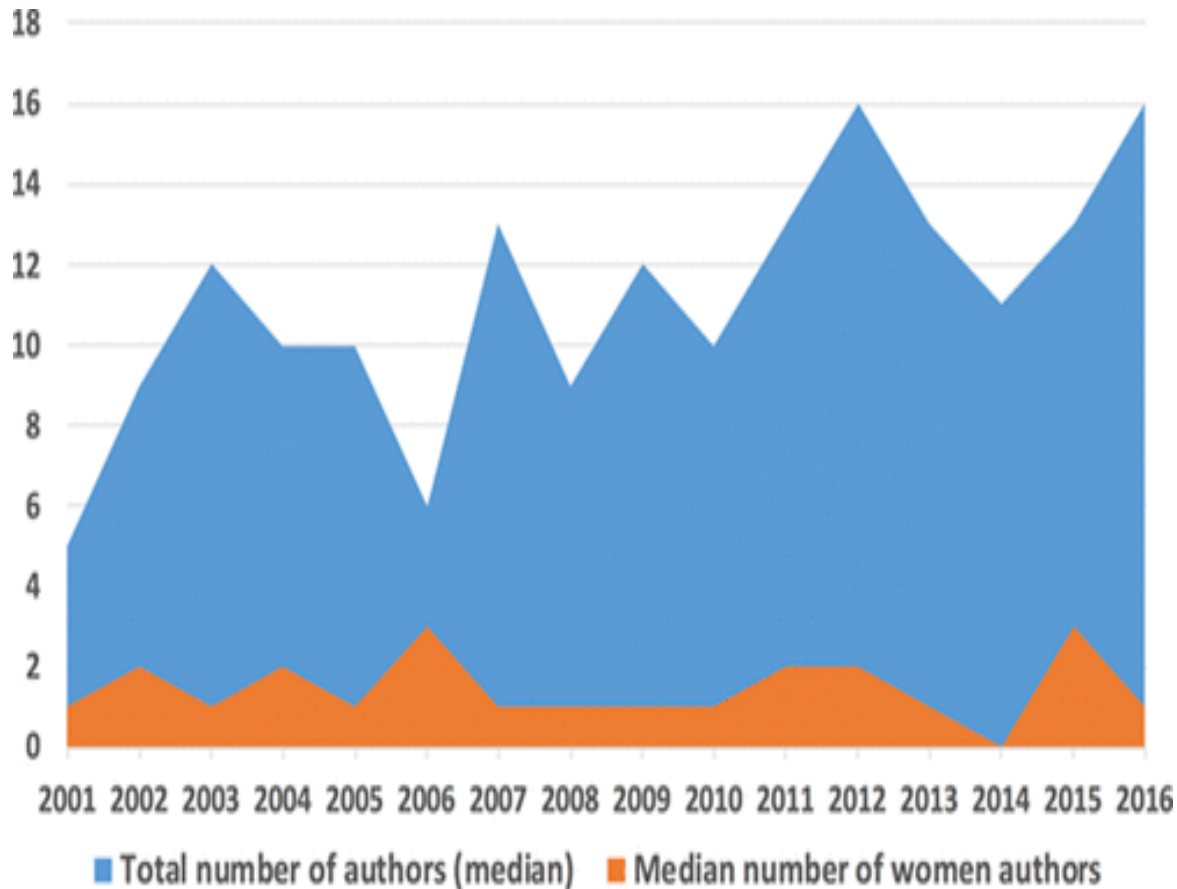


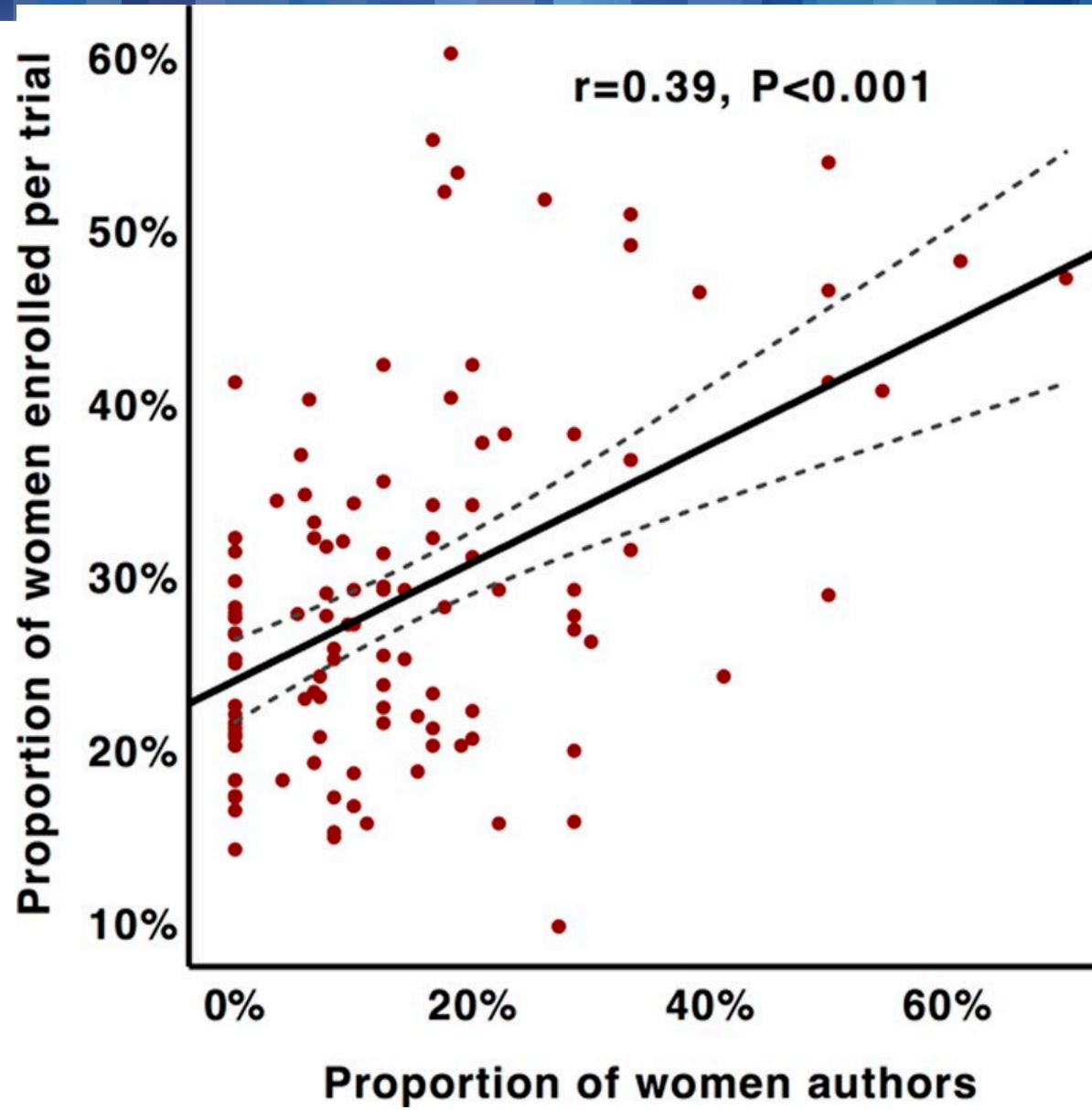






# Representation of Women Authors in Heart Failure Guidelines and Clinical Trials







# Prioritize diversity in the clinical research workforce

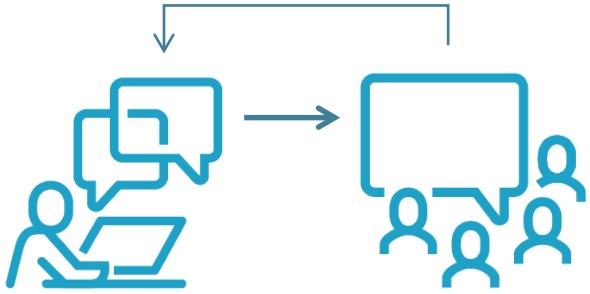
- Hiring individuals from under-represented groups
- Offering support and mentorship of their research endeavors



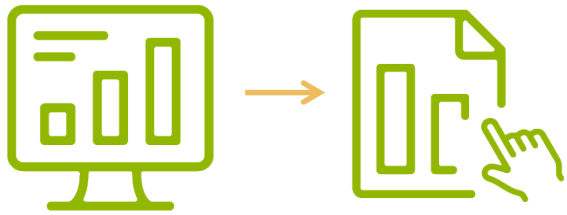
## Clinical Trials Research: Upping Your Game

Professional Development for Cardiologists and PhD  
Researchers Seeking to Succeed in Clinical Research

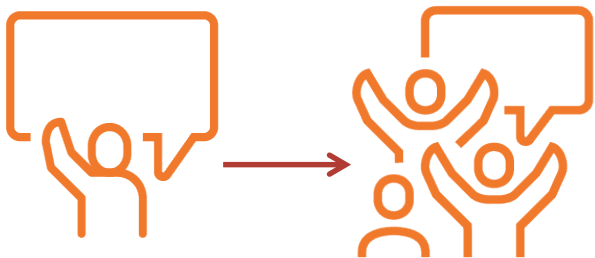




**Build Engagement and Partnerships with Participants.**



**Improve Accessibility of Clinical Trials,**



**Improve Representation Among Clinical Investigators**