

# Equity in Evidence: Addressing Minority Representation in Research

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# Disclosures

The planners and speakers have indicated that there are no relevant financial relationships with any ineligible companies to disclose.



# Objectives

- 1 Review historical context surrounding underrepresentation of minority groups in research, as well as biases in healthcare
- 2 Identify how underrepresented communities in research impact the healthcare system
- 3 Discuss socioeconomic challenges to equity in research and how to mitigate these challenges
- 4 Identify strategies to diversify research participation

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# Abbreviations

- AIDS = Acquired Immunodeficiency Syndrome
- ASCVD = Atherosclerotic Cardiovascular Disease
- BIPOC = Black, Indigenous, and People of Color
- CFTR = Cystic Fibrosis Transmembrane Conductance Regulator
- FDA = Food and Drug Administration
- GLP1 = Glucose-like Peptide 1
- HIV = Human Immunodeficiency Virus
- HTN = Hypertension
- IRB = Institutional Review Board
- LGBTQIA+ = Lesbian/Gay/Bisexual/Transgender/Queer/Intersex/Ally community
- NIH = National Institute of Health
- PrEP = Pre-exposure prophylaxis
- RCT = Randomized clinical trial
- SDI = Social Deprivation Index
- SDOH = Social Determinants of Health
- SES = Socioeconomic status
- SGLT2i = Sodium Glucose Transport-2 inhibitor
- T2DM = Type 2 Diabetes Mellitus



01

# Introduction



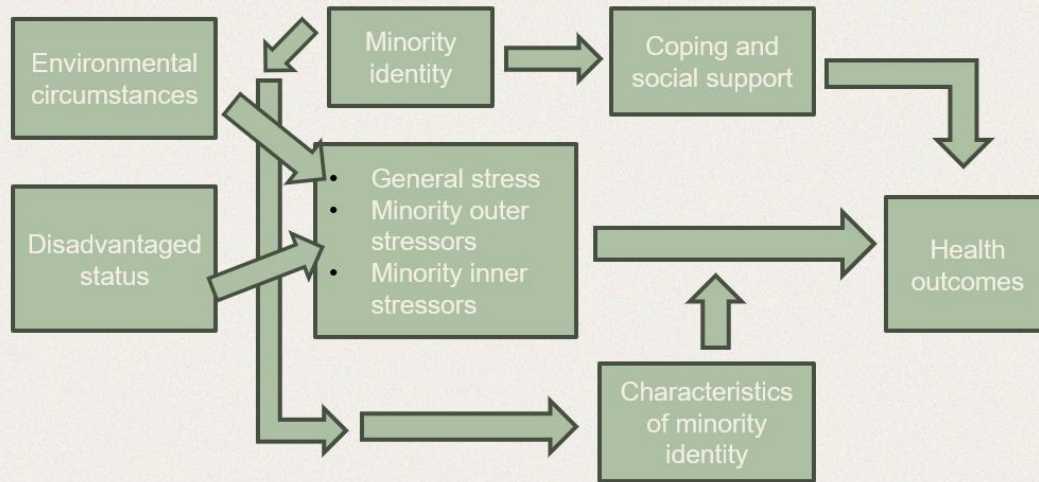
# Definition of a Minority Group

- Population subgroup that differs from the dominant majority



# Minority Stress Model

- Theory that minority stress is produced by excess exposure to social stress
- Focuses on those who are in the LGBTQIA+ community, but also has been expanded to those who are at disadvantaged status through race and ethnicity





# Advances in Ethical Considerations Throughout Research



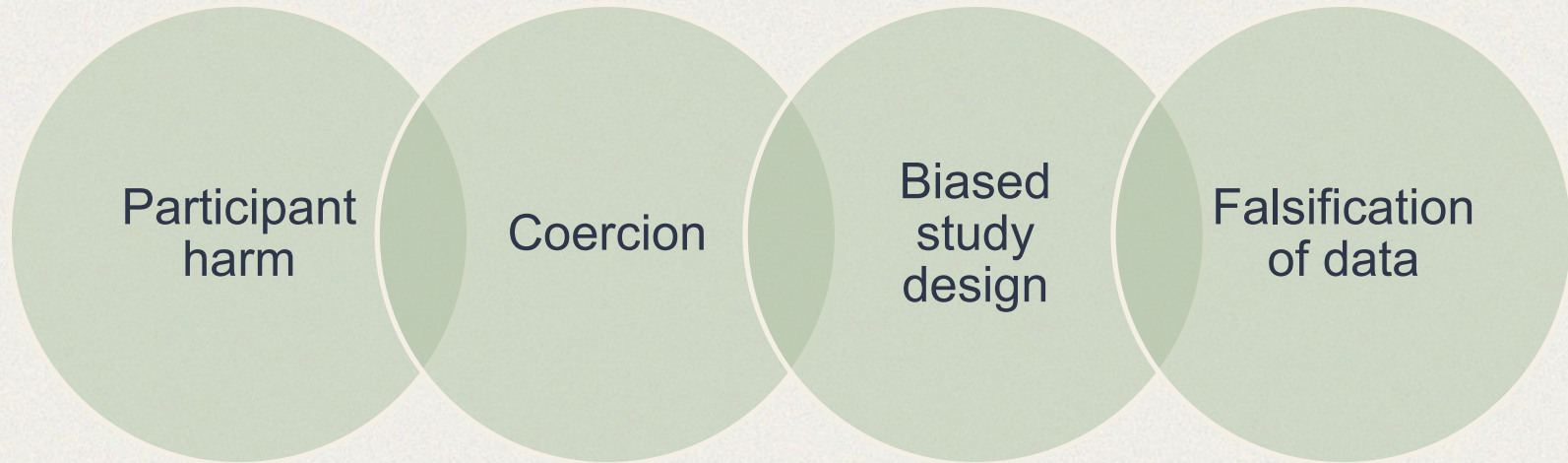
# 4 Core Principles of Ethical Research

1. **Nonmaleficence** -> Obligation to do no harm to the patient
2. **Autonomy** -> Patients should be allowed to make their own choices
3. **Justice** -> fair, equitable and appropriate distribution of healthcare resources
4. **Beneficence** -> Obligation of not just avoiding harm but also benefiting patients to promote their welfare





# Unethical Study Designs in Research



# Monitoring of the Patient Recruitment Process: Institutional Review Boards

Institutional Review Boards (IRB) – provide protection for human research participants through the review of research proposals

Committee reviews risks/benefits to subjects, equitable selection, protection of privacy, and informed consent process

Specific requirements

- At least 5 members of varying backgrounds
- At least 1 member knowledgeable about any regularly researched vulnerable groups
- Members report and recusal for conflicts of interest



# Overview: Research Recruitment Process

## Decide on research plans and goals

- Define target population

## IRB approval

- Ensuring materials are submitted to the IRB for ethical oversight

## Informed Consent

- Participants must sign an informed consent to participate

## Screening for inclusion criteria

- All participants who show interest in the study may not meet all inclusion criteria

## Choosing research advertising channels

- Offline versus online pros and cons?

## Begin research process

- Assign participants into the study



# Generalized Issues in Research Recruitment

- **Participant retention**
  - Informed consent documents
  - Incentivizing: good or bad?
- **Gaining appropriate sample size to meet power**
  - Overestimation of participants meeting inclusion criteria and willingness to enroll in trials
- **Lack of awareness of clinical trials**
  - Literacy rates
  - Rural areas and academic medical centers





# Advertisement Required Information

Institutional affiliation

Purpose of the research

Who is eligible to participate

Description of participation benefits

Brief statement regarding incentives of participation

Research location

Contact information

# Pros and Cons of Research Recruitment Methods: Advertising

	PROS	CONS
ADVERTISING	<ul style="list-style-type: none"><li>• Larger reach</li></ul>	<ul style="list-style-type: none"><li>• Literacy rate</li><li>• Access to social media</li><li>• Low retention</li></ul>

Rare Disease Clinical Research Network: evaluating direct-to-consumer advertising to see if this was an effective strategy to retain participation in rare disease studies

Outcome: successful in accumulating 40.1% lead generation for those to be enrolled in studies, but only 3 participants were enrolled over 6 studies



# Effectiveness and Ethical Incentivization: RETAIN study

<b>Objective</b>	<b>To determine whether incentives improve enrollment in RCTs or serve as undue inducements</b>  <b>Primary outcome: proportion of people assigned to each recruitment strategy that consented to participate</b>
<b>Methods</b>	Recruited patients who had not heard about the incentivization for the trial and had participated in either the smoking cessation or ambulation trial  Incentives included: \$0, \$200, \$500 for smoking trial and \$0, \$100, \$300 for ambulation trial  Undue inducements: measured through comparing income, financial well-being and the Research Attitude Questionnaire
<b>Results</b>	Smoking trial: 21.8%, 35.9%, and 47.1% for \$0, \$200, \$500 (OR, 1.7; [95% CI, 1.34-2.17; P<0.001])  Ambulation trial: 45.4%, 48.1%, 43% for \$0, \$100, \$300 (OR, 0.88; [95% CI, 0.64-1.22; P<0.45])

**Conclusion:** In these 2 RCTs, it was shown that there were no ethical problems with incentives for research participation



# Assessment Question #1

A new clinical trial for a groundbreaking medication is launched and has 500 participants. Of the 500 participants, 250 end up developing a severe side effect. Despite being given supportive care, the side effect did not resolve which results in the discontinuation of the trial.

Which of the four core principles of ethical research does this **most closely** represent?

- A. Justice
- B. Nonmaleficence
- C. Autonomy
- D. Beneficence





02

# Impact on the Healthcare System

# Harms of Non-Inclusive Research

1. Monetary Costs

2. Underrepresentation in Clinical Trials

3. Missed Opportunities for Treatment



# Monetary Costs: ALLHAT Trial

- Background:
  - Hypertension (HTN) treatment can cost up to \$37 billion annually
  - **Purpose: to determine whether the occurrence of fatal coronary heart disease or nonfatal myocardial infarction is lower for high-risk patients treated with amlodipine, lisinopril, or doxazosin each compared with chlorthalidone**
    - Pre-defined subgroups: Diabetes, older, and Black patients
- Methods
  - Randomized double-blind, multicenter clinical trial
  - Participants: men and women 55 YO+ who had stage 1 or 2 HTN with at least 1 additional risk factor for a coronary heart disease event (T2DM, cigarette smoking, etc.)
  - 3 arms all compared with chlorthalidone: amlodipine, lisinopril and doxazosin

**Primary outcome:** Fatal coronary heart disease or nonfatal myocardial infarction combined

**Secondary outcomes:** All-cause mortality, fatal and nonfatal stroke, combined coronary heart disease, and combined cardiovascular disease

# Monetary Costs: ALLHAT Trial Results

Outcome (Participants)	Chlorthalidone N = 9886 – All other racial groups N = 5369 – Black Americans		Lisinopril N = 5844 – all other racial groups N = 3210 – Black Americans	
All cause mortality	1382 (16.9%)	821 (17.9%)	794 (16.7%)	520 (18%)
Stroke	418 (5.4%)	257 (6%)	245 (5.3%)	212 (8%)
	RR, 1; 95% CI, 0.85 - 1.17		RR, 1.4; 95% CI, 1.17-1.68	

- Strengths: first study that included more representation of women and Black Americans with a large population, long term follow-up
- Limitations: angiotensin-receptor blockers were not included, higher step-up regimen in the ACE inhibitor group

**Conclusion: In Black patients with hypertension, a thiazide-type diuretic or calcium-channel blocker are preferred over ACE inhibitors as initial single-drug therapy due to stroke risk**



# How Inclusivity Decreased Costs?

- **Less expensive main-stay medication**

Lifetime cost of care	Chlorthalidone	Amlodipine	Lisinopril
	\$53,500	\$58,300	\$57,200

- **Less risk of hospitalization due to stroke risk**



# Underrepresentation: Diabetes and Anticoagulation

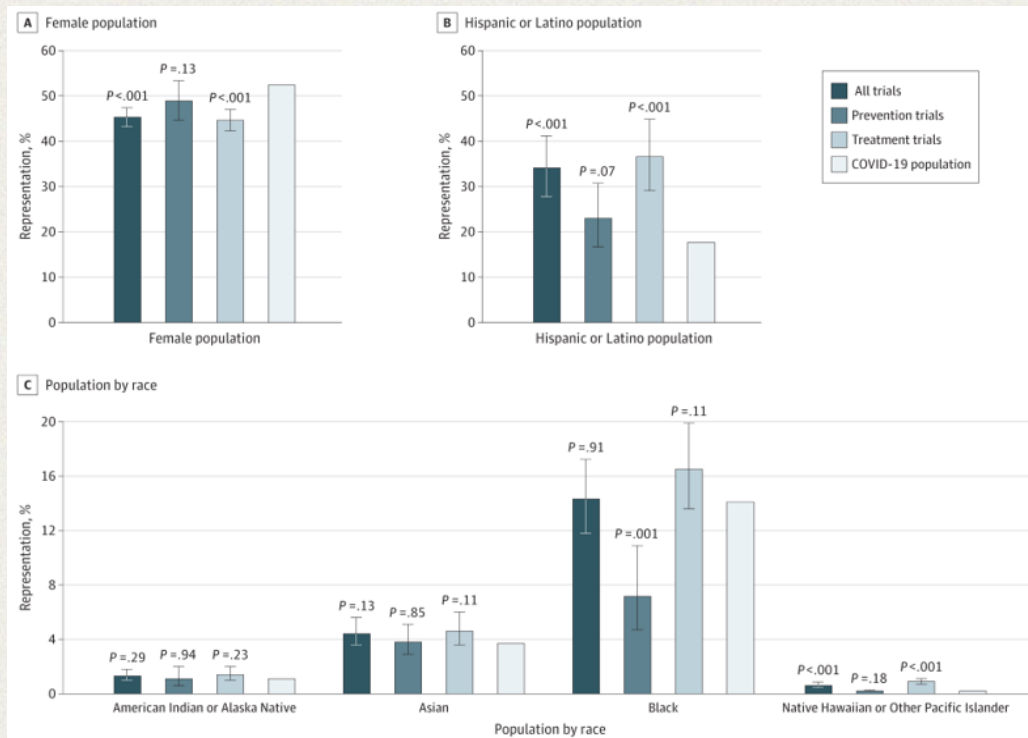
- Diabetes
  - Hispanic/Latino (17%) and Black individuals (60%) more likely to have T2DM than non-Hispanic White individuals
  - Lack of inclusion in GLP-1 and SGLT2i trials
- Warfarin dose adjustments
  - Genetic variability: CYP2C9
  - Did not know until 2013 that genotypes could have an effect on warfarin dosing



# Underrepresentation Effects on Diagnosis

- Cystic fibrosis: Newborn Screenings
  - In BIPOC: more likely to carry CF transmembrane conductance regulator variants – omitted from newborn screening panels which leads to delayed diagnosis and treatment
  - 2024 US CF Foundation Patient Registry – Does not identify full CFTR genotype for non-White patients (exact percentages in article), signifying racial inequity
  - 2008 study – Influenced racial biases by suggesting individuals with African ancestry have high immunoreactive trypsinogen levels without the presence of CF
    - Third-tier sweat testing only conducted in infants who screened positive in the second tier with only 1 or 2 CFTR variants

# Underrepresentation in Clinical Trials: COVID-19





# Missed Opportunities for Treatment

- Inclusive research leads to innovative medicine reflective of our patient population
  - Expand access to medications
  - Influence practice guidelines
  - Introduce novel mechanisms for pharmacotherapy

PCSK9 gene discovered in  
Montreal and Oslo



Dallas Heart Study identified  
mutations in PCSK9 in Afro-  
American patients



Development of PCSK9  
inhibitors for lipid-lowering



## Assessment Question #2

Which statement below is **FALSE**?

- A. Medical Mistrust scales are used most frequently to gauge patient outlook on providers/hospital groups.
- B. Research that lacks inclusiveness will cost researchers money due to incomplete or faulty data.
- C. Racial underrepresentation can lead racial bias and medical fallacies.
- D. Noninclusive research only waste money for researcher but does not directly harm patients.





**03**

# **Barriers to Inclusion**

# Social Determinants of Health (SDOH)

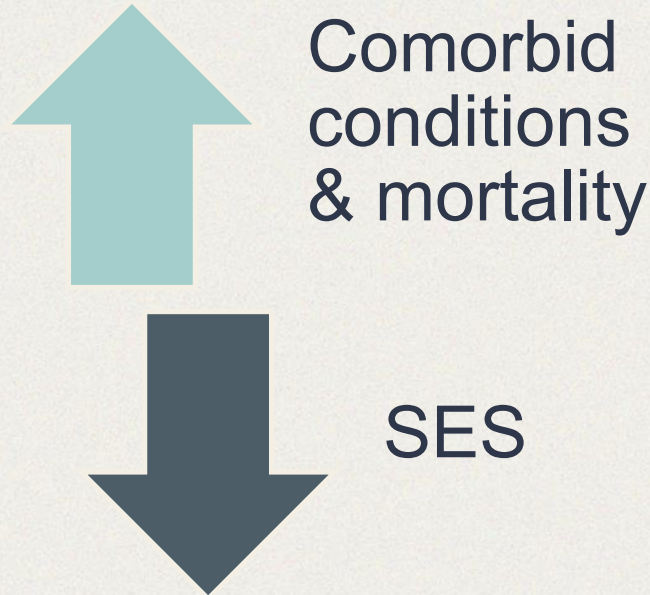
Definition: the structural political, economic, social and cultural systems that stratify societies and differentially shape living conditions across the life course





# Socioeconomic Status (SES)

**Definition:** a key determinant of health referring to the social class or income of an individual or group





# Socioeconomic Status Hypotheses

## Social Mobility Hypothesis

Individuals of low SES are likely to remain in this status

Individuals of high SES are likely to accumulate benefits

## Critical Period Hypothesis

Children of low SES are exposed to harmful factors that negatively impact long-term health



# Health Care Access and Quality

	Personal Health Literacy	Organizational Health Literacy
<b>Definition</b>	The degree to which individuals have the ability to find, understand, and use information and services to inform health-related decisions and actions for themselves and others	The degree to which organizations enable all individuals to find, understand, and use information and services to inform health-related decisions and actions for themselves and others
<b>Category</b>	Social risk	Social determinant of health
<b>Impact</b>	Low personal health literacy = high risk of misunderstanding	Low organizational health literacy counteracts high personal health literacy

# Assessment Question #3

Which of the following would NOT be a useful strategy to improve organizational health literacy

- A. Provide all pharmacy employees with mandatory onboarding training for strategies to communicate medication changes to patients at discharge.
- B. Create an annual updates resource for healthcare professionals to understand where current resources can be located.
- C. Refer patients with questions regarding insurance to speak with their primary care physician
- D. Create a panel of pharmacy staff to review and update patient education sheets periodically, implementing feedback from patients.



# Language Barriers

In the past 90 days, have you engaged with a non-English speaking patient?

# Language Barriers

- Lack of translated research materials
  - Participants resorted to self-translation
  - Complicates already unfamiliar research process
- In the UK, 64% of recruiting studies excluded participants who were unable to communicate in English
- Analysis of U.S. clinicaltrials.gov studies
  - Over 2,700 trials had English language requirements
  - Only 390 (2.71%) mentioned accommodation of non-English language
  - Types of studies more likely to require English proficiency
    - Government-funded
    - Depression, diabetes, breast cancer, prostate cancer



# IRB Literacy Requirements

- Enterprise IRB protocol available within PolicyTech
  - Outlines strategies to include vulnerable patients
    - Deaf, blind, illiterate, unable to read or write
    - Require use of in-person, phone, or video conferencing interpreter
  - Reading level: 8<sup>th</sup> grade
- Strategies to improve comprehension
  - Improve readability of consent forms
  - Add additional educational materials or training for participants
  - Video resources for the trial instead of written handouts

# Cultural Barriers

- Cultural perceptions of information varies between ethnicities
- Stigmas:
  - Disease state (e.g. mental health, sexually transmitted disease)
  - Incentives may be perceived as inappropriate

## **Solution: Community Champion**

- Familiar with cultural significance
- Involved and trusted in their community
- Assist with recruitment efforts



# Barbershop Study: Community Champion

## Background

- Pharmacist-led interventions improve health outcomes
- Non-Hispanic black men have highest rates of hypertension-related death in the United States
- Previous studies lack enrollment of non-Hispanic black men

## Population

- 319 non-Hispanic black male patrons with SBP 140 mm Hg or more
- Setting: 52 black-owned barbershops

## Intervention

- Barbers encouraged meetings with pharmacists

## Primary Outcome

- Reduction in SBP at 6 months

## Results

- Intervention group SBP reduction by 27 mm Hg compared to 9.3 mm Hg control

# Social

## Overview of Social Strategies

- Shorter questionnaires
- Providing transportation vouchers
- Collecting participant responses via electronic or paper means rather than verbally to research personnel
- Socially oriented incentives

## Discussion

- Identified 4 behavioral approaches to improve recruitment and retention
- Non-financial incentive interventions are low to no cost once developed

## Results

- Strategies that build social connections build trust
- Reducing financial, time, or social barriers had either a significantly positive or null effect



# Mistrust in Healthcare

- Transgender healthcare
  - US Transgender Survey – done every few years and shows how those who are transgender rate their healthcare in opposition to their cisgender counterparts
  - Results of 2022 survey showed 24% of respondents avoided healthcare due to being mistreated as a trans person (this was similar to 2015's percentage)
- Several different validated scales are used to determine medical mistrust
  - Group-Based Medical Mistrust Scale, Medical Mistrust Index, and Health Care System Distrust Scale: most frequently used
  - Found differences among the scales in the object of mistrust (system vs. Individual physician) and specific group that experienced the mistrust

# Stigma in Healthcare

- HIV and AIDS trials
  - AIDS epidemic – first recognized in 1981, but no effective medication until 1987
    - Zidovudine trial – Baseline characteristics: 92% primarily white males
      - Could not be generalized to the overall population
  - HIV-specific criminal laws published in 35 states that punished behaviors that might transmit HIV
    - Led to less disclosure of HIV status, resistance to HIV testing, and those who did not want to get involved in clinical trials due to these consequences
- Activism ultimately increased the exploration of different types of drugs with less side effects
- Descovy for PrEP: Only had been studied in males and transgender women, but not cisgender females
  - 2019: Women account for 20% of reported HIV cases due to heterosexual intercourse and IV drug use



# Economic Status

- Worldwide, 50% of research participants are considered high-income
- Barriers to research participation:
  - **Transportation**
  - Childcare
  - Elderly or ill family members
  - PTO or sick days
- National economic challenges
  - ~3.3 billion people live in countries prioritizing debt payments over health investments



04

# Strategies to Diversify Research Participation



# Example: PREVENT Calculator

## ASCVD Risk Estimator

- Historically used to assess 10-year risk of ASCVD
- Includes **age**, **sex**, and **race**

## PREVENT Calculator

- **Removed race** as a factor
- Inclusion of **zip code** to estimate **social deprivation index (SDI)**

# Social Deprivation Index (SDI)

Living in  
poverty

<12 years of  
education

Single-parent  
household

Living in  
rented housing  
units

Living in  
overcrowded  
housing units

Households  
without a car

Non-employed  
adults <65  
years of age



# SDOH: Healthy People 2030

Economic  
Stability

Education  
Access and  
Quality

Health Care  
Access and  
Quality

Neighborhood  
and Built  
Environment

Social and  
Community  
Context

# SDOH: Healthy People 2030

## Economic Stability

- Employment
- Food Insecurity
- Housing Instability
- Poverty

## Education Access and Quality

- Early Childhood Development and Education
- Enrollment in Higher Education
- High School Graduation
- Language and Literacy

## Health Care Access and Quality

- Access to Health Services
- Access to Primary Care
- Health Literacy

## Neighborhood and Built Environment

- Access to Foods That Support Healthy Dietary Patterns
- Crime and Violence
- Environmental Conditions
- Quality of Housing

## Social and Community Context

- Civic Participation
- Incarceration
- Social Cohesion



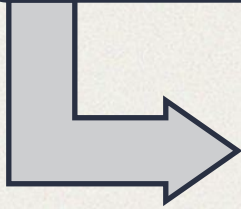
# Key Points

- People in minority groups are not inherently less likely to participate in research
- Asian, Black, Latinx Americans, American Indian/Alaska Native individuals are not less likely to participate in research
- People in rural areas not less willing to participate
  - **Many socioeconomic barriers limit participation in research**
  - **Efforts should be increased to provide inclusive opportunities**

# Federal Guidance

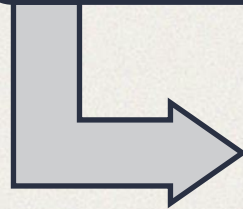
## FDA Drug Trial Snapshots

- Published in 2015
- Reported demographic characteristics of clinical studies



## NIH Good Clinical Practice Training

- Funding opportunity announcements (FOAs)
- Financial penalties for noncompliance



## Present Day Reporting

- 30% of participants are from ethnic minority groups
- Inconsistencies in data reporting
- Difficult to assess extent of participation in trial



# Building Trust: Examples of Bias

Implicit

Explicit

Geographic

Technical

Framing Effect

Overconfidence

# Types of Bias in Research

## Geographic Bias

- Associated with **publication bias**

## Technical Bias

- “Cherry-picking”

## Selection Bias

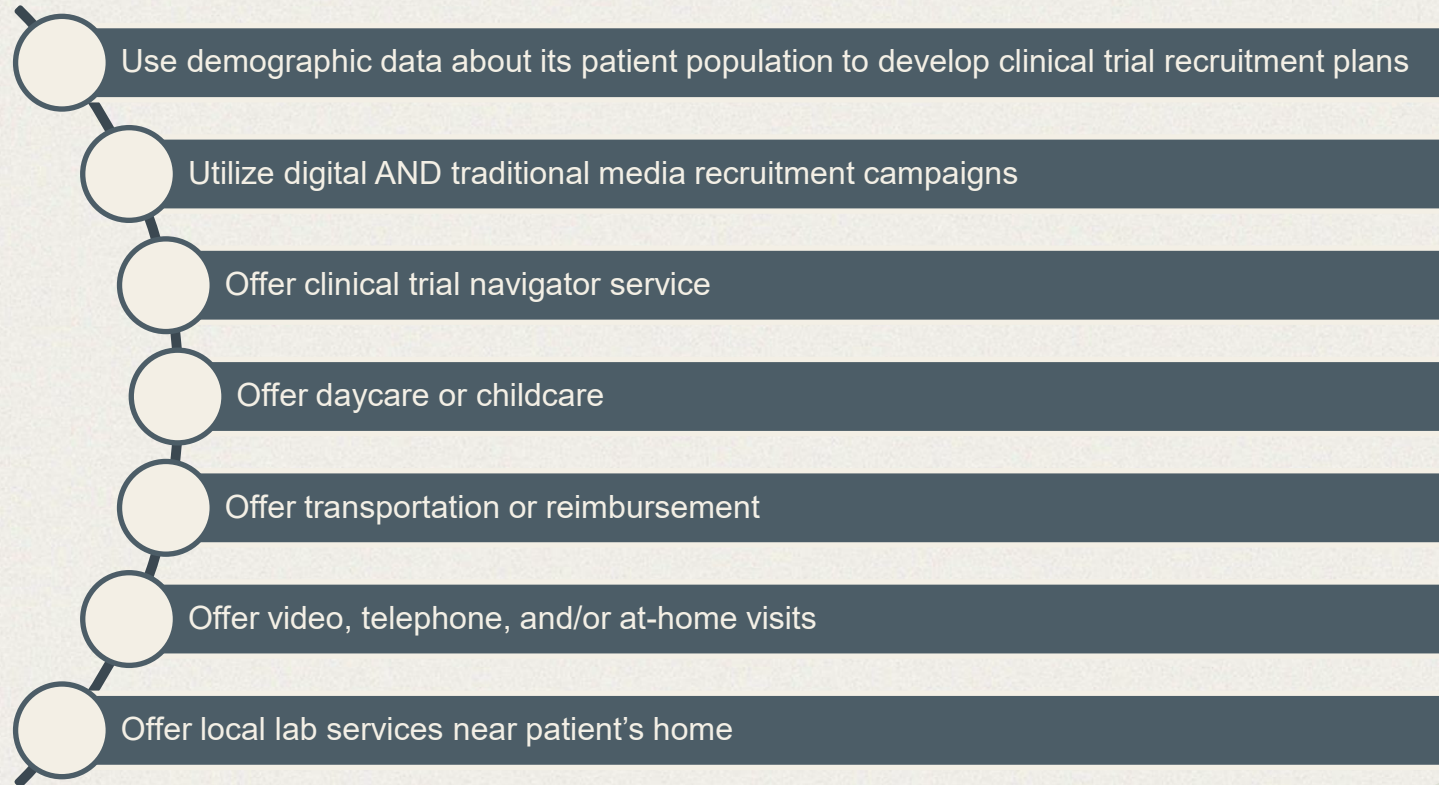
- Sampling bias
- Self-selection (volunteer) bias
- Undercoverage bias



# Reviewing Strategies to Improve Research Participation

Title	Mapping Strategies for Reaching Socioeconomically Disadvantaged Populations in Clinical Trials
Background	Low SES patients less likely to participate in clinical trials despite high rates of chronic medical conditions
Methods	<p>Survey distributed to 6690 sites</p> <ul style="list-style-type: none"><li>• 492 responses from 381 sites (7.4%)</li><li>• 47.% located in the South</li><li>• 16.1% located in the Midwest</li></ul>
Site types	<ul style="list-style-type: none"><li>• For profit (57.5%)</li><li>• Nonprofit or governmental (42.5%)</li><li>• Urban (94.4%)</li><li>• Suburban (2.1%)</li><li>• Rural (3.5%)</li></ul>

# Reviewing Strategies to Improve Research Participation: Survey





# Reviewing Strategies to Improve Research Participation: Results

For-profit sites more often provided:

- After-hours visits
- Financial compensation
- Assistance with transportation

Organization partnerships

- For-profit: civic groups, faith-based organizations, health services
- Nonprofit: patient advocacy groups

Most sites (for-profit and nonprofit):

- Do not collect socioeconomic information

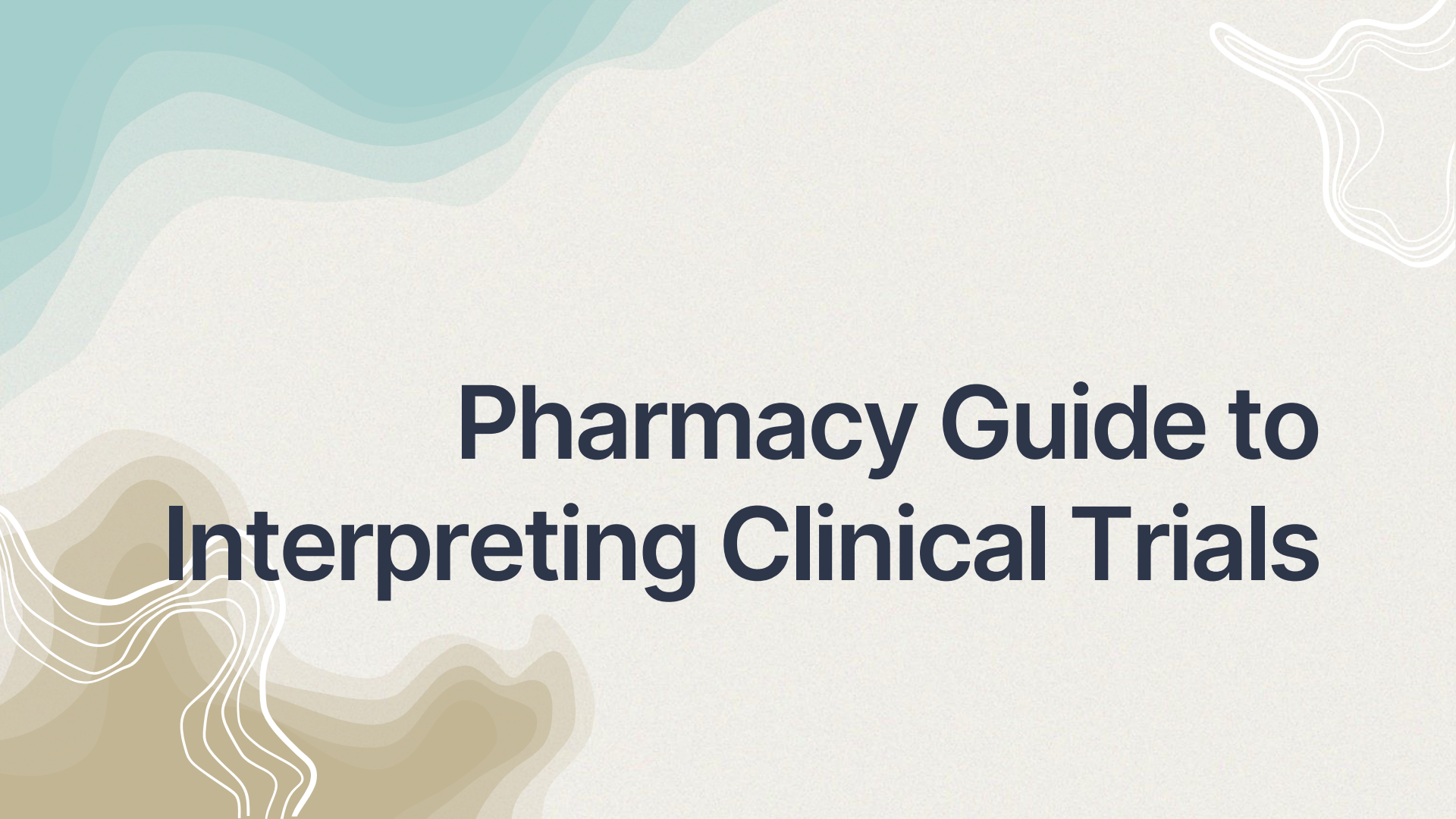
Adoption of strategies to engage socioeconomically diverse populations may help minimize barriers to participation

# Direct Benefits of Inclusive Research: Turning a Corner? The EMPACTA Study

- Studied the safety and efficacy of tocilizumab in patients who were not receiving mechanical ventilation
- Overall result: Tocilizumab reduced likelihood of progression to mechanical ventilation/death but did not improve survival

Population group	Percentage of representation
Hispanic/Latino	56%
Black	14.9%
American Indian/Alaskan Native	12.7%
Non-Hispanic White	12.7%
Unknown race/ethnic group	3.7%





# **Pharmacy Guide to Interpreting Clinical Trials**

# Evaluation of Primary Literature Tips and Tricks: Methods

Questions to ask:

- **Inclusion and exclusion criteria:** Does this reflect a population as a whole affected by this disease state?
  - Selection bias
  - Subject recruitment methods
- **Blinding:** What type of blinding was used and was it an appropriate way to perform this particular study?
  - Broken blinds
- **Selection criteria:** Was the sample selected randomly from different communities or was it mostly one subgroup?



# Evaluation of Publishing Journal

## Questions to ask:

1. Where (geographically) are published trials and articles coming from?
2. Is information regarding funding easily accessible?
3. Are published materials presented in bias-free language and community-driven language guidelines?
4. Do research trials report sample justifications?



**Let's Practice!**



# Prasugrel versus Clopidogrel in Patients with Acute Coronary Syndromes

## Background

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To compare prasugrel and clopidogrel in terms of death from cardiovascular causes, nonfatal myocardial infarction or nonfatal stroke and assess major bleeding risk

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## Study design

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Randomized into 2 groups (unstable angina/non-ST elevation myocardial infarction and ST-elevation with myocardial infarction)

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## Findings

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12.1% of patients receiving clopidogrel and 9.9% of patients receiving prasugrel had a primary endpoint outcome. Major bleeding was observed in 2.4% of patients receiving prasugrel and 1.8% receiving clopidogrel

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## Impact

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This study emphasized the importance of weighing the risks and benefits of using clopidogrel vs. prasugrel

# Baseline Characteristics

Characteristic	Prasugrel (N = 6813)	Clopidogrel (N = 6795)
Unstable angina or NSTEMI (%)	74	74
Age		
Median (yr)	61	61
≥ 75	13	13
Female sex (%)	25	27
White race (%)	92	93

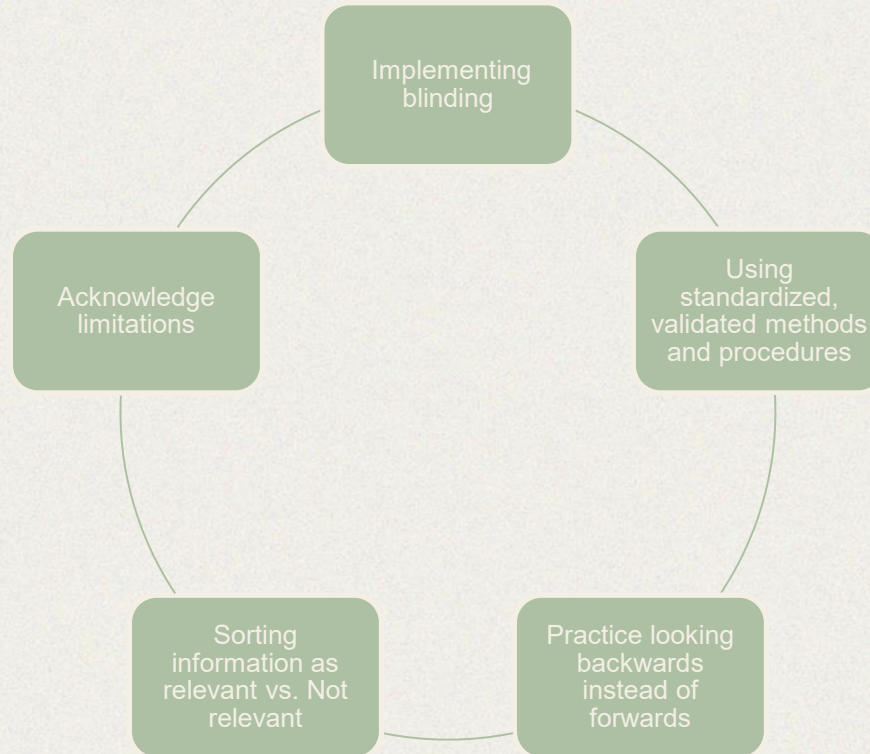


# Assessment Question #4

Based on the previous slide, which of the following baseline characteristics may reduce applicability to a larger patient population in practice? (select all that apply)

- A. Unstable angina or STEMI
- B. Age
- C. Sex
- D. Race

# How We Can Improve Equity in the Research Space as Healthcare Professionals





# Summary

- All trials cannot be generalized depending on the population tested in and must be analyzed in a way to not perpetrate bias
- Although there has been a move towards equity in research, there is still much to be done
- By having more inclusive recruitment strategies and addressing bias, researchers can move towards better diversity representation in studies

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# Questions?

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