

# The Use of Race and Ethnicity in Biomedical Research - Meeting 3

NATIONAL  
ACADEMIES *Sciences  
Engineering  
Medicine*

## SESSION V: Industry Perspective on the Use of Race and Ethnicity in Research

January 31, 2024

Pierre R. Theodore, M.D.

Head Patient Inclusion and Health Equity

Genentech

D&I Diversity  
& Inclusion

GENENTECH CONFIDENTIAL & PROPRIETARY

**Genentech**  
*A Member of the Roche Group*

Alzheimer's  
Development Risk



2x

Greater for Black Americans

AD Clinical Trial  
Participants:  
2001-2019



1.2%

Black Americans

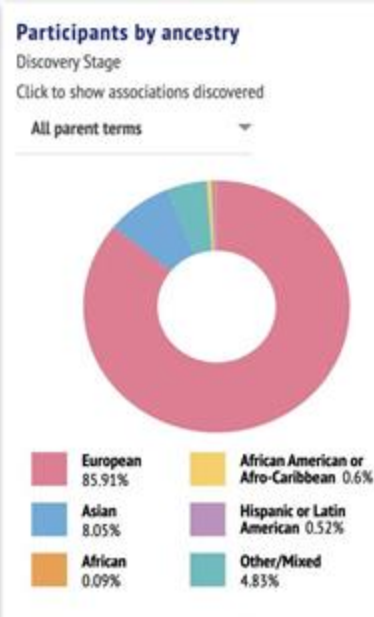
95%

White Americans

Source: STAT News

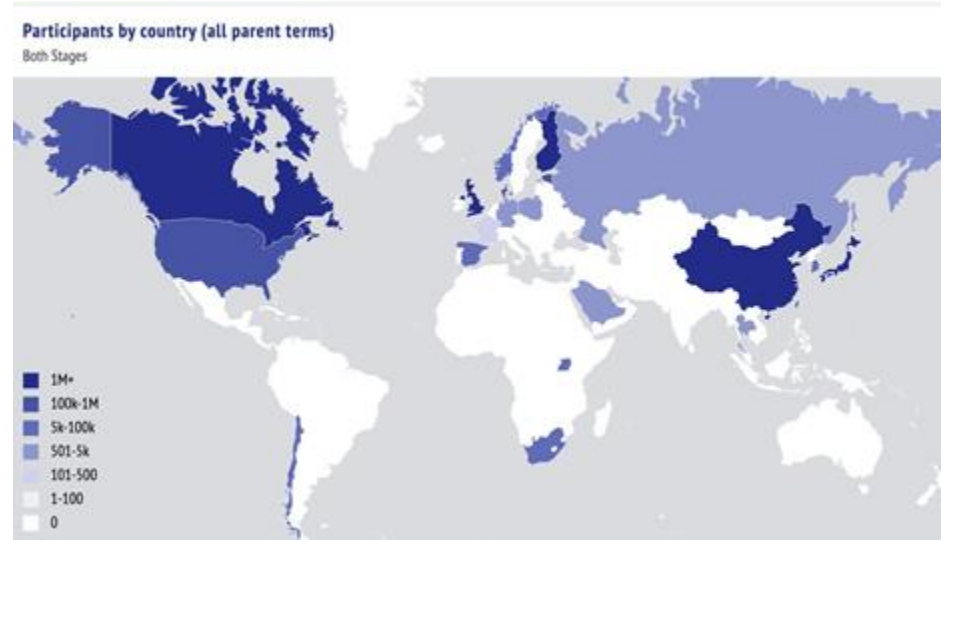
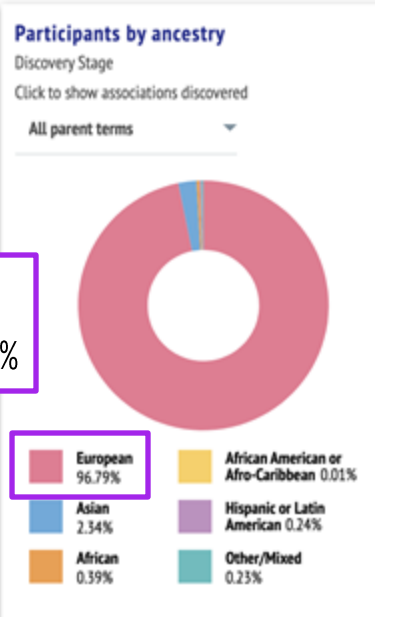
# UNDERSTUDIED POPULATIONS IN GENOMIC DATA YIELDS BIASED GENETIC DISCOVERIES (2023)

## 2022



↑  
10.88%

## 2023



<https://gwasdiversitymonitor.com/>

Available genomic data and medical research is predominantly based on European ancestry, leaving significant amounts of world wide genotypic and phenotypic variation undiscovered.

# ACKNOWLEDGE THE PAST TO REBUILD TRUST IN RESEARCH STUDIES.

Ensure we ask underrepresented patients if they want to participate in studies. **Just ask.**



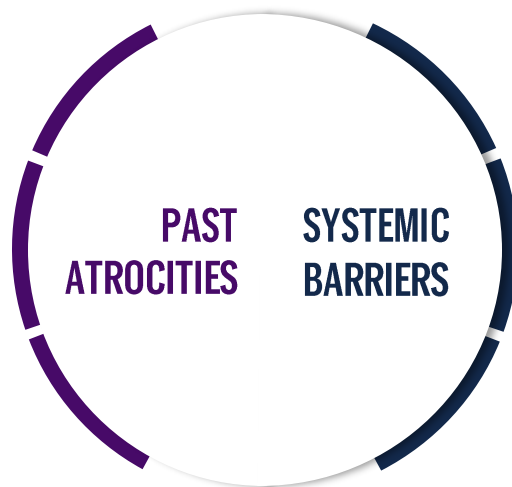
U.S. Public Health Service  
Syphilis Study at Tuskegee



Cincinnati Radiation  
Experiments



Contraceptive trials  
in Puerto Rico



Lack of strategy for  
health equity



Lack of targeted  
outreach



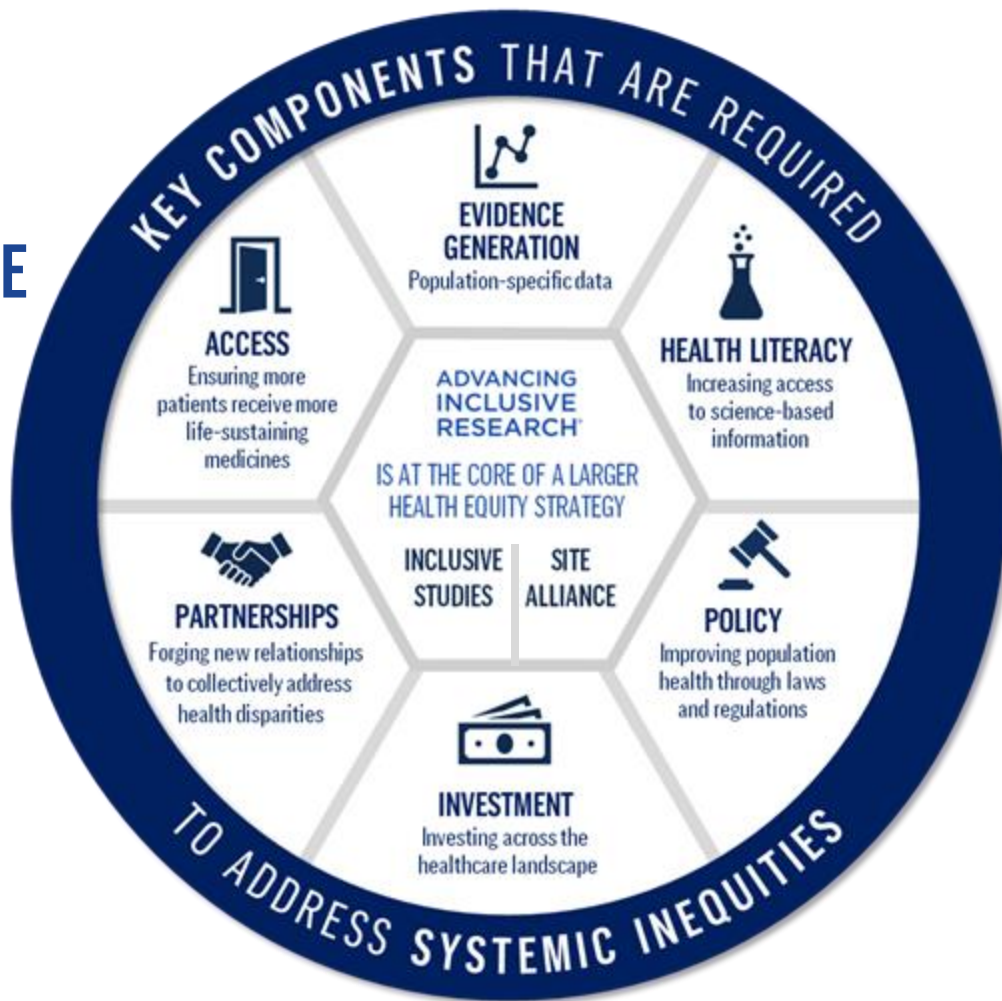
Stereotypical  
assumptions and bias



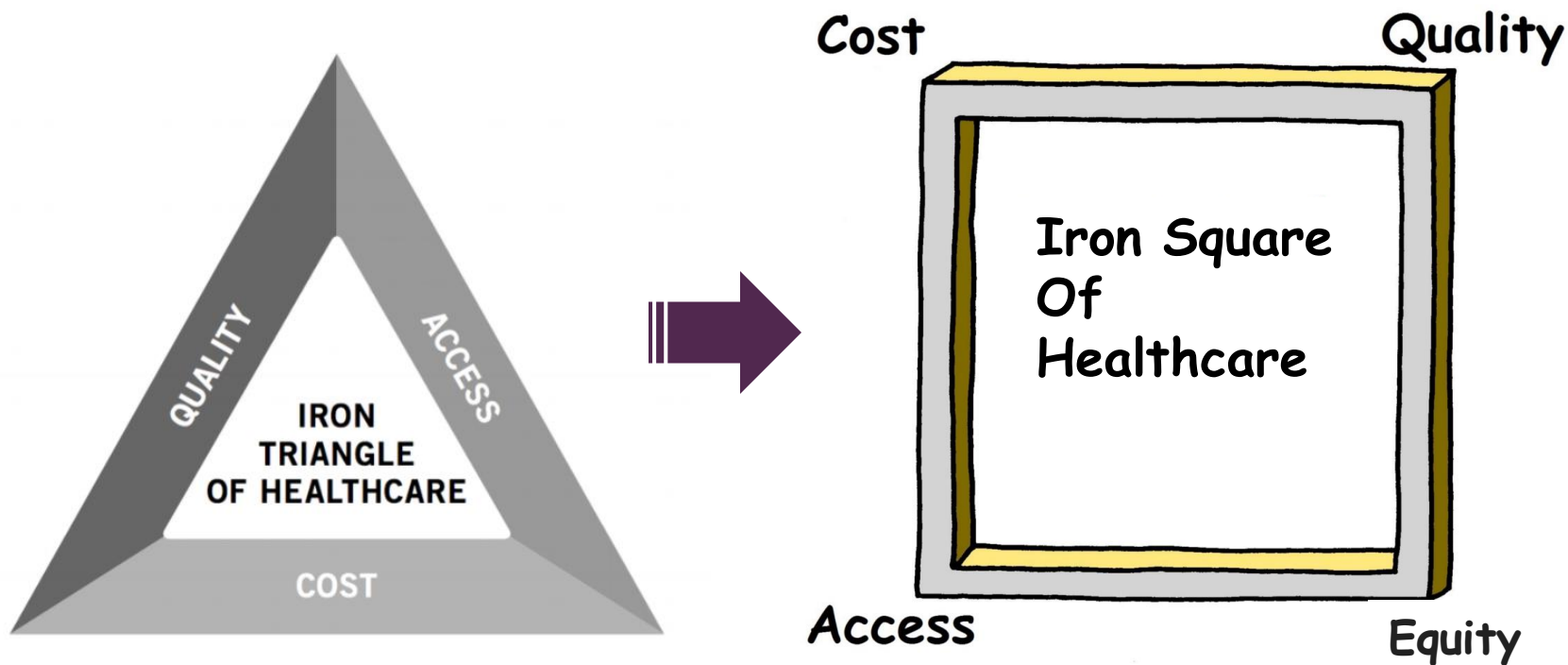
Despite these atrocities and barriers,  
**85% of patients** said they were **‘very willing’** or **‘somewhat willing’** to participate in studies\*

# BOLD LEADERSHIP IS REQUIRED TO ADVANCE HEALTH EQUITY

LEAVE NO PATIENT BEHIND,  
DESIGN WITH EQUITY IN MIND



# The Iron Square of Healthcare Value



# Data Informed Site Selection



ADVANCING INCLUSIVE RESEARCH & HEALTH EQUITY

ALL MOLECULE TEAMS include population specific assessments and inclusive research action plans

ADVANCING INCLUSIVE RESEARCH®  
SITEALLIANCE

THE AIR SITES  
ENROLL A MORE  
DIVERSE POPULATION,  
FASTER

~2X

Enrollment Rate  
of diverse patients<sup>1,2,3</sup>



## 6 ALLIANCE ONCOLOGY SITES:

Delivering a patient population

**76% more diverse** than their study peers<sup>2,3,4</sup>

Are the sole recruiter of **Black and/or Hispanic** patients in **1/5** of our studies<sup>2,4</sup>

## 3 OPHTHALMOLOGY SITES:

Deliver a patient population

**68% more diverse** than their study peers<sup>2,3,4</sup>

Enroll diverse patients at a rate

**60% faster** than their study peers<sup>2,3,4</sup>

# NEW OMNIBUS LAW: CLINICAL TRIAL DIVERSITY STRATEGY CODIFIED INTO LEGISLATION— December 2022



## DIVERSITY ACTION PLANS Sec. 3601

### REQUIRES SPONSORS TO SUBMIT DIVERSITY ACTION PLAN FOR ALL PHASE 3 CLINICAL TRIALS OF NEW DRUGS, INCLUDING:

- Enrollment goals disaggregated by age group, sex, and racial and ethnic demographic characteristics
- Rationale for enrollment goals
- Explanation of how sponsor plans to meet enrollment goals

Plans must be submitted but no later than submission of protocol for Phase 3 study (or other pivotal study of the drug)

<https://www.congress.gov/bill/117th-congress/house-bill/2617/text>

<https://www.advi.com/insight/house-and-senate-pass-the-consolidated-appropriations-act-of-2023/>