



CLINICAL TRIAL PERSPECTIVE

Advancing Health Equity in Medical Devices

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Divisional Vice President, Global Clinical Affairs, Abbott's Vascular Business

6 | September | 2023

Conflict of Interest

JENNIFER JONES-MCMEANS, PHD

ABBOTT EMPLOYEE

We help people live fuller, healthier lives, maximizing their potential at all ages and stages of life

CARDIOVASCULAR CARE

Keeping hearts healthy with medical technologies that help people and their doctors better manage cardiac health



NEUROMODULATION CARE

Treating chronic pain and movement disorders by targeting specific areas of the brain



DIABETES CARE

Giving people with diabetes the freedom to continuously monitor and track their glucose levels with unsurpassed 14-day accuracy and no painful finger sticks



NUTRITION

Using the latest science to create better ways to nourish bodies from infancy to adulthood



DIAGNOSTICS

Providing accurate, timely information to guide effective treatment decisions



MEDICINES

Helping people get and stay healthy with quality medicines they can trust



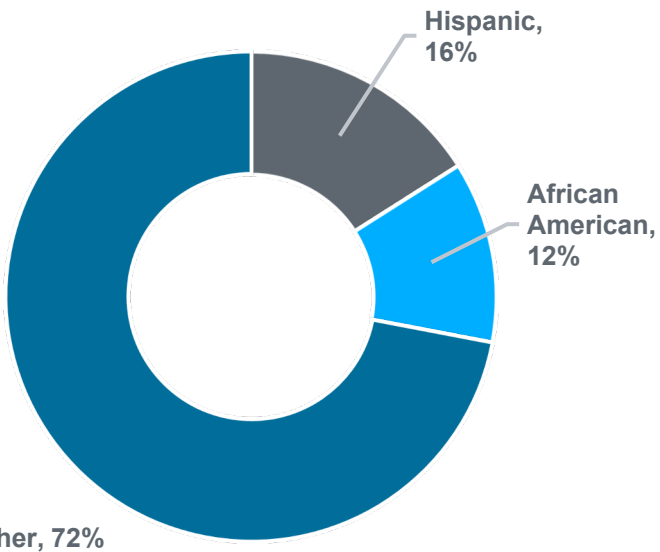
CLINICAL TRIALS HAVE A DIVERSITY PROBLEM.

THAT'S WHY WE'RE TAKING ACTION
TO MAKE RESEARCH MORE INCLUSIVE.

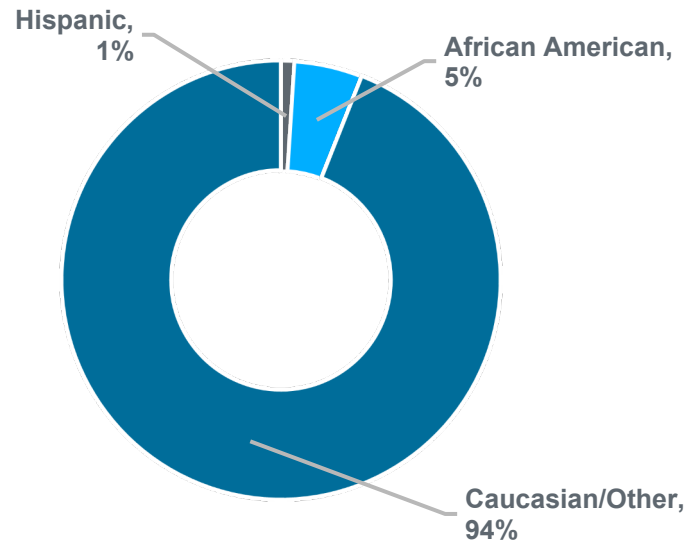


Clinical Trials Have Not Always Represented US Population

U.S. POPULATION



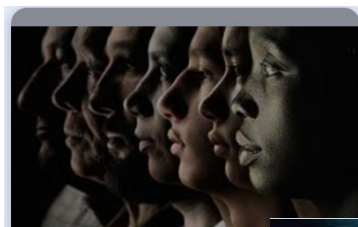
CLINICAL TRIAL PARTICIPANTS



(Society for Women's Health Research and United States Food and Drug Administration Office of Women's Health, 2011)

Commitment and Momentum to Improve Clinical Trial Diversity

Commitment Across Pharmaceutical and Medical Device Industry



Johnson & Johnson
Clinical Trial Diversity



"Increased diversity in clinical trials can yield more insightful and comprehensive findings and translate into medicines that can improve outcomes for patients from every background."

Kim Ribeaux
Director, Clinical Trials



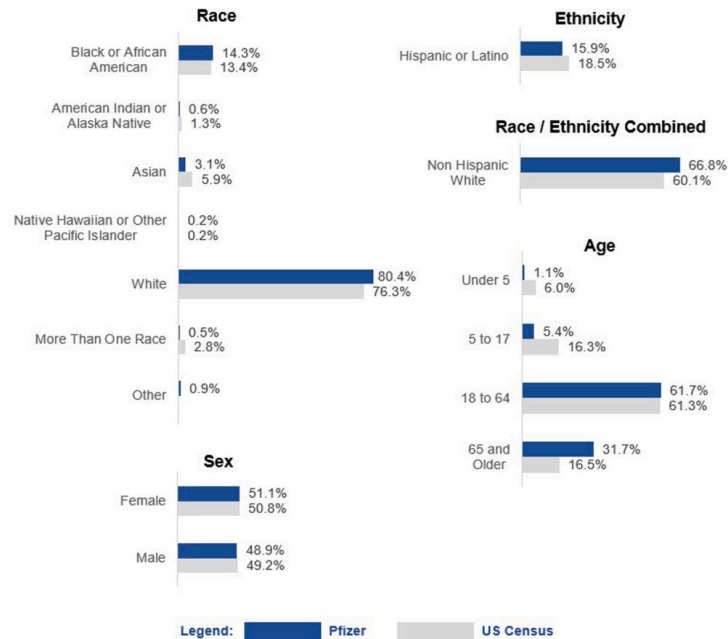
Genentech
Genentech: Advancing Inclusive Research



Pfizer
Diversity in Our Clinical Trials | Pfizer



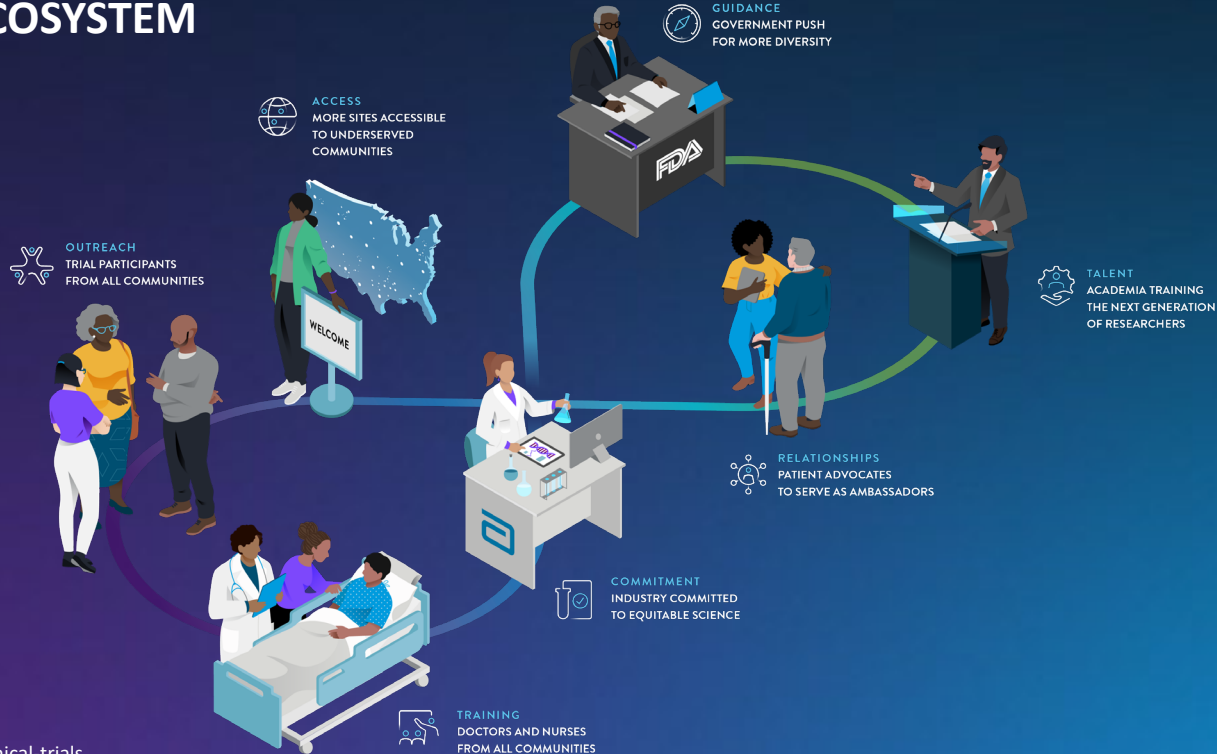
More than half of Pfizer trials achieved census levels for Black/African American participants
White participants and Hispanic or Latino participants



CLINICAL TRIAL

Patient Focused Team Sport

AN IDEAL ECOSYSTEM



abbott.com/diversity-in-clinical-trials

Proprietary and confidential — do not distribute

Social Determinants of Health



Economic Stability

- Employment
- Income
- Expenses
- Debt
- Medical bills
- Support



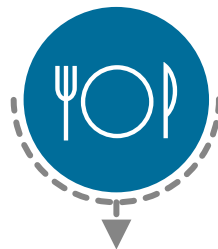
Neighborhood and Physical Environment

- Housing
- Transportation
- Safety
- Parks
- Playgrounds
- Walkability
- Zip Code / geography



Education

- Literacy
- Language
- Early childhood education
- Vocational training
- Higher education



Food

- Hunger
- Access to healthy options



Community and Social Context

- Social integration
- Support system
- Community engagement
- Discrimination
- Stress



Healthcare System

- Health coverage
- Provider availability
- Provider linguistic and cultural competency
- Quality of care

Health Outcomes

Mortality, Morbidity, Life Expectancy, Healthcare Expenditures, Health Status, Functional Limitations

Diversity in Clinical Trials: Barriers to Tackle

5 CRITICAL BARRIERS TO ENROLLMENT OF DIVERSE POPULATIONS

1

Mistrust

2

Lack of comfort
with process

3

Lack of
information

4

Time and
resource
constraints

5

Lack of
awareness

Clark et al. Curr Probl Cardiol 2019;44:148172

ABBOTT

Removing Barriers for Patient Access



TRANSPORTATION
SUPPORT



LODGING
& MEALS



HOME
VISITS



PATIENT
WEBSITE



TRANSLATION
SERVICES



PATIENT VIDEO
& RADIO
MEDIA TOUR

DECENTRALIZING TRIALS

Subbiah et al. Nature Medicine Volume 29 | January 2023 | 49–58

FDA Draft Guidance: Decentralized Clinical Trials for Drugs, Biological Products, and Devices Guidance for Industry, Investigators, and Other Stakeholders, May 2023

Proprietary and confidential — do not distribute

Clinical Trial Evolution: Future Vision & Future Reality | October 19, 2023

LIFE-BTK Webpage (www.LIFE-BTK.com)



THE LIFE-BTK STUDY

WHAT IS PAD AND CLI?

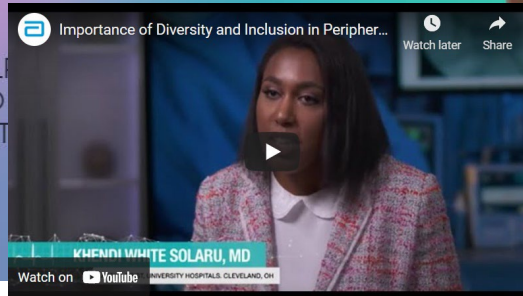
Facts About PAD and Critical Limb Ischemia

8.5 MILLION PEOPLE

8.5 million people in the United States have PAD,² but 75% of adults are not aware of the disease³



Diabetes, hypertension, smoking and obesity are major risk factors¹²



Resource for patients and families on PAD and clinical trials

Proprietary and confidential — do not distribute

Special focus on inclusion of diversity by gender race/ethnicity and community

Patients able to see others like themselves

ABBOTT BREATHE Trial PATIENT ADVISORY PANEL



Patient Involvement

Patient advocacy organization to recruit a racially diverse patients experienced pulmonary embolism (PE)

Patients survey experience with PE and their feelings towards clinical trial participation



Patient Advisory Panel

Select group of patients (~20) to participate in a live moderated patient advisory panel to provide specific feedback on BREATHE clinical trial design

Feedback from patient advisors to improve the design and conduct



Ultimate Objective

The BREATHE Patient Advisory Panel input on study logistics, improve enrollment and retention of a racially and ethnically representative population, and provide a positive experience to trial subjects

Diversity in Research Initiative

In November 2021, Abbott launched our “Diversity in Research” initiative to develop a more inclusive clinical trial ecosystem in the U.S.



Nearly **300 new scholarships** for historically black colleges and universities (HBCUs) and minority nursing associations



Diversity in Research Medical Advisory Board and corresponding internal steering committee



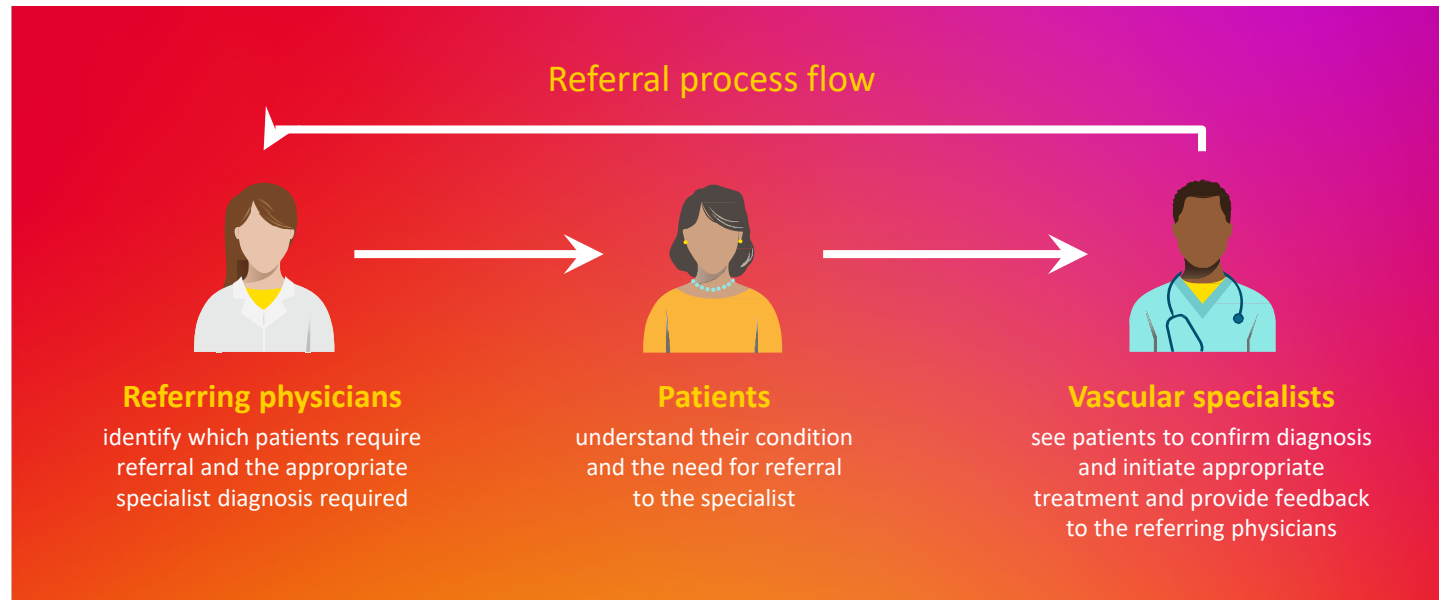
Internal funding to support tactics to drive diverse patient enrollment in select Abbott trials



Convening patient advocates, industry experts, trialists and thought leaders to develop and publish an **open-source perspective for industry** to highlight opportunities to diversify trials

CLEAR CAN HELP PAD PATIENTS TO RECEIVE A TIMELY DIAGNOSIS FOLLOWED BY APPROPRIATE TREATMENT

CLEAR facilitates the education and referral process with advantages for three key stakeholders:



CLINICAL TRIALS

Future Vision to Future Reality



**Evolve to meet
societal needs**



**Tools for
patients, families
and physicians**



**Patients at the
center of multi-
level care team**



Abbott