INDUSTRY ADVISORY FORUM

AMERICAN COLLEGE of CARDIOLOGY®

@ACCINTOUCH

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The ACC Thanks You For Your Partnership!

The ACC would like to thank its partners for their contribution to the success of the Industry Advisory Forum (IAF) and their commitment to advancing cardiovascular health.

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Join the Conversation on Twitter

#TransformCVCare

#ACCInnovation

Edward T. A. Fry, MD, FACC, FSCAI
President , American College of Cardiology
Chair, Ascension National CV Service Line
Ascension St. Vincent Heart Center
Indianapolis, IN

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Nov. 8, 2022
New York City

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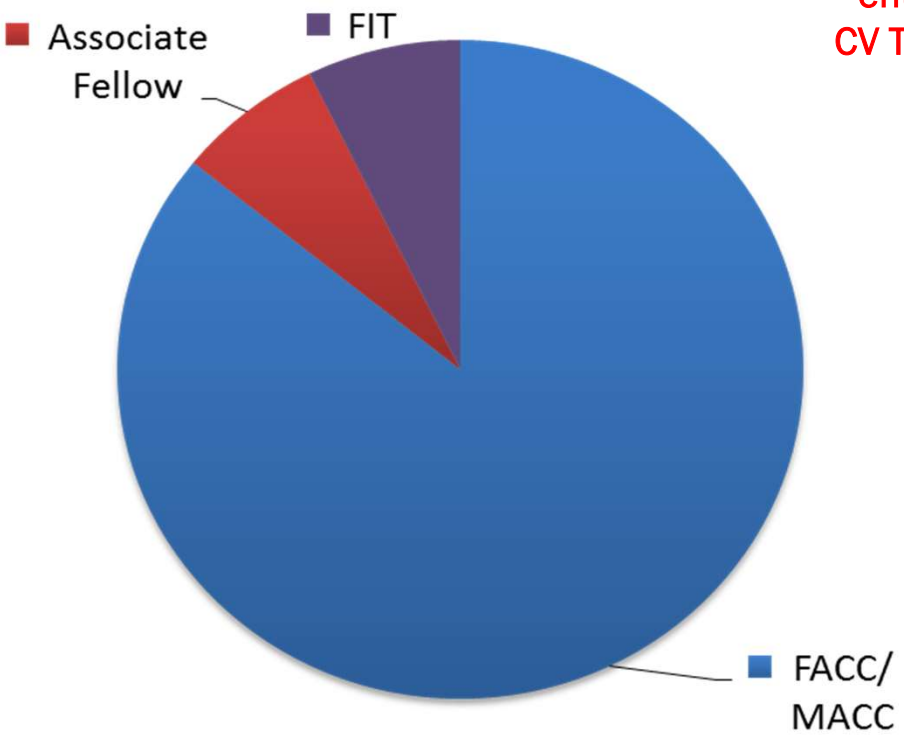
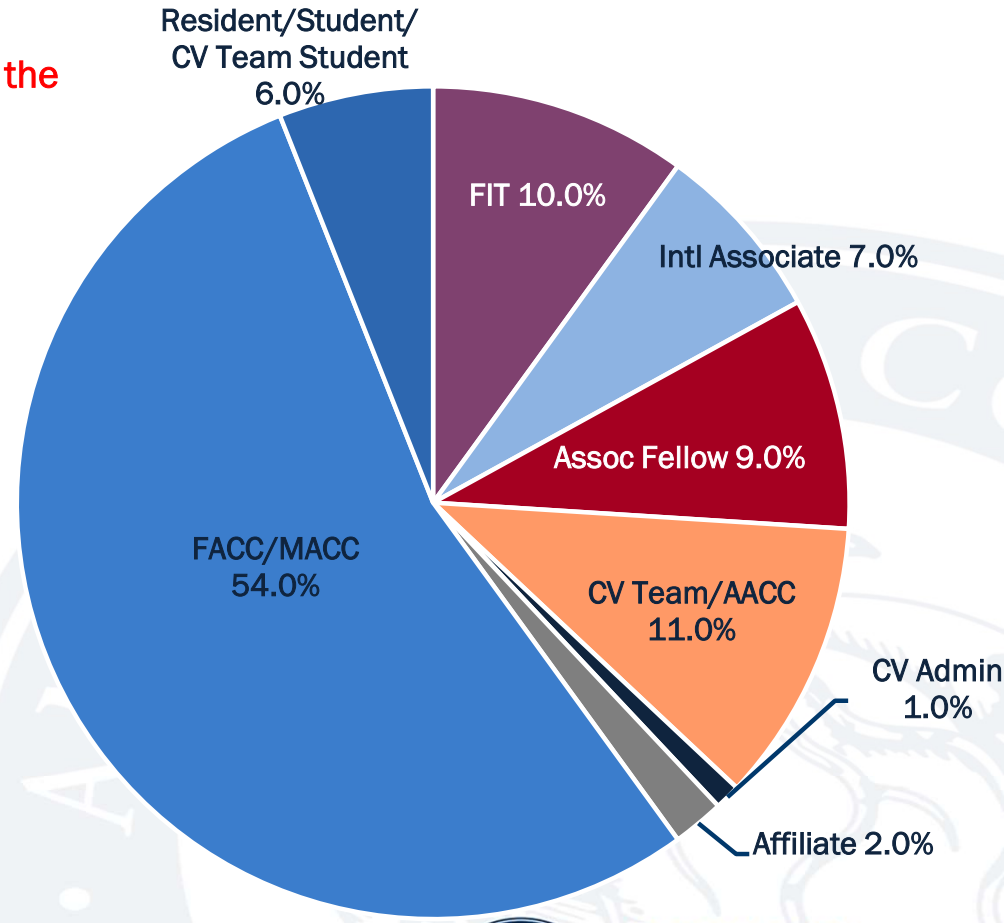
ACC in 2000 (26,000 Members)



Professional Home for the entire CV Team

ACC Today (57,000+ Members)



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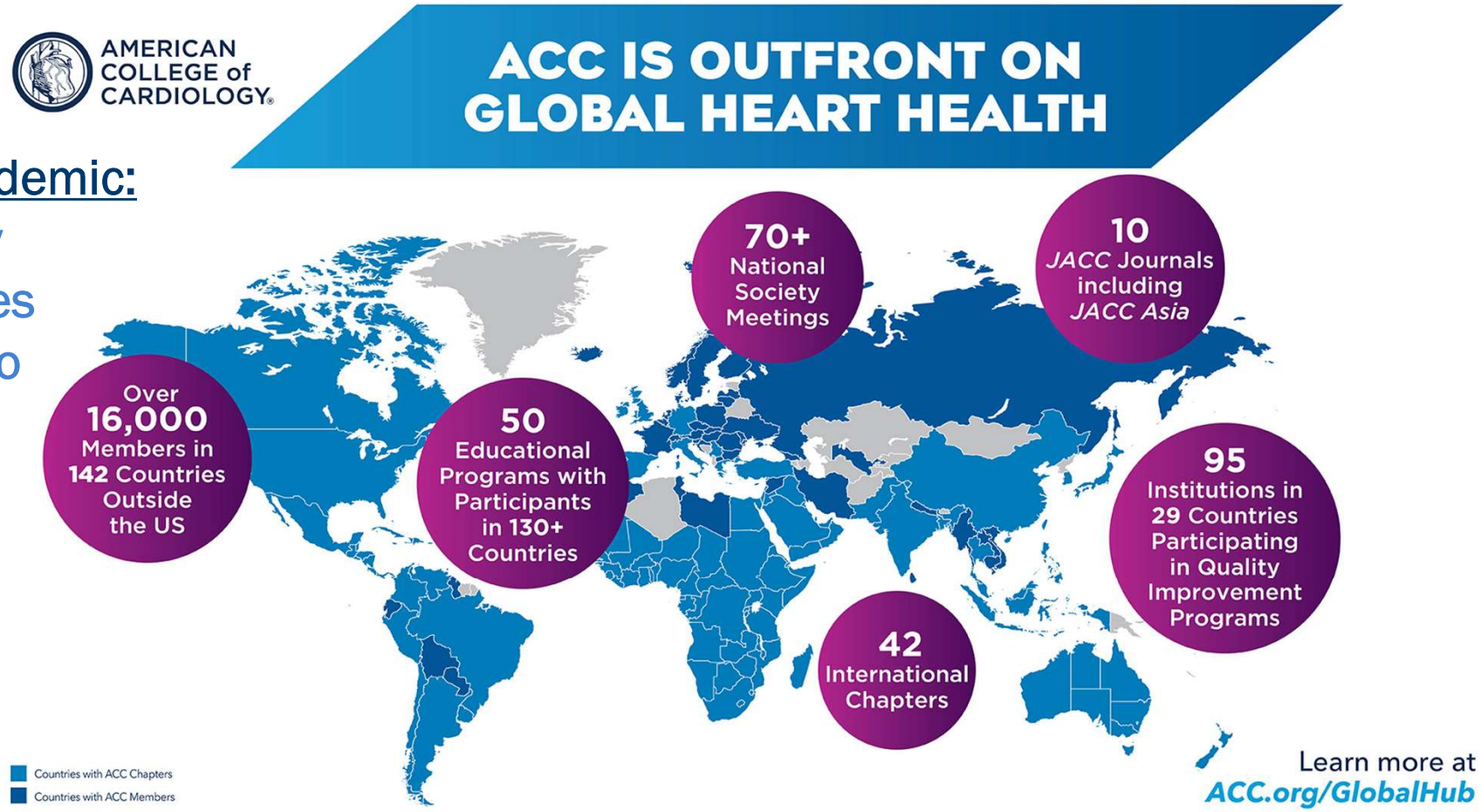
ACC International/Global Acceleration: Footprint

Non-Communicable Diseases – 70% of global mortality



Global Epidemic:

- Obesity
- Diabetes
- Tobacco
- HTN

What is Impacting CV Clinicians in 2022?

Constant Change
Accelerating Change

Georgia
CHAPTER

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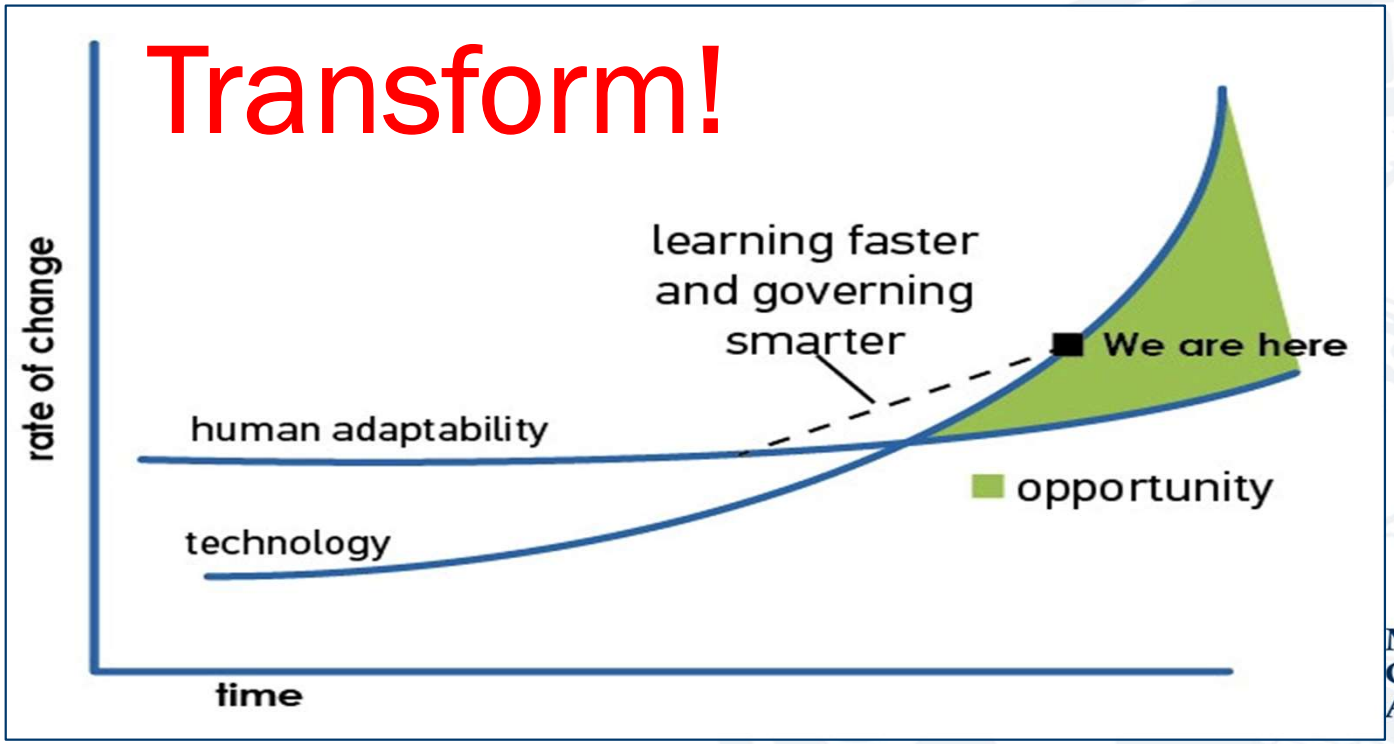
Change as the new constant:

Acceleration of Change: Eric "Astro" Teller's Curve

Thank You for Being Late – *Thomas Freidman, 2016, p. 34*



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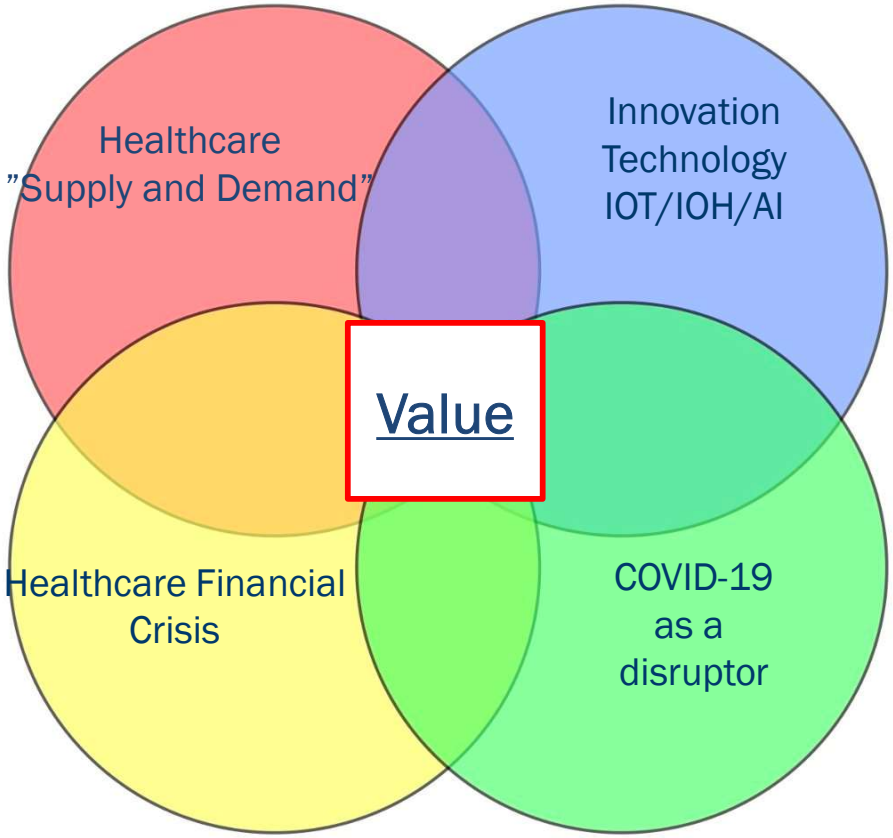
Why Do We Need Care Transformation?

Workforce crisis
11K turn 65 y/o daily
Fragmented System



Opportunities:
Increased connectivity
Digital world
Digital health tools

Declining life-expectancy
Deferred/delayed care
Impact of SDOH's
Lack of Health Equity

Health care inflation
CMS broke in 2030
Health systems in the red
Unsustainable FFS system

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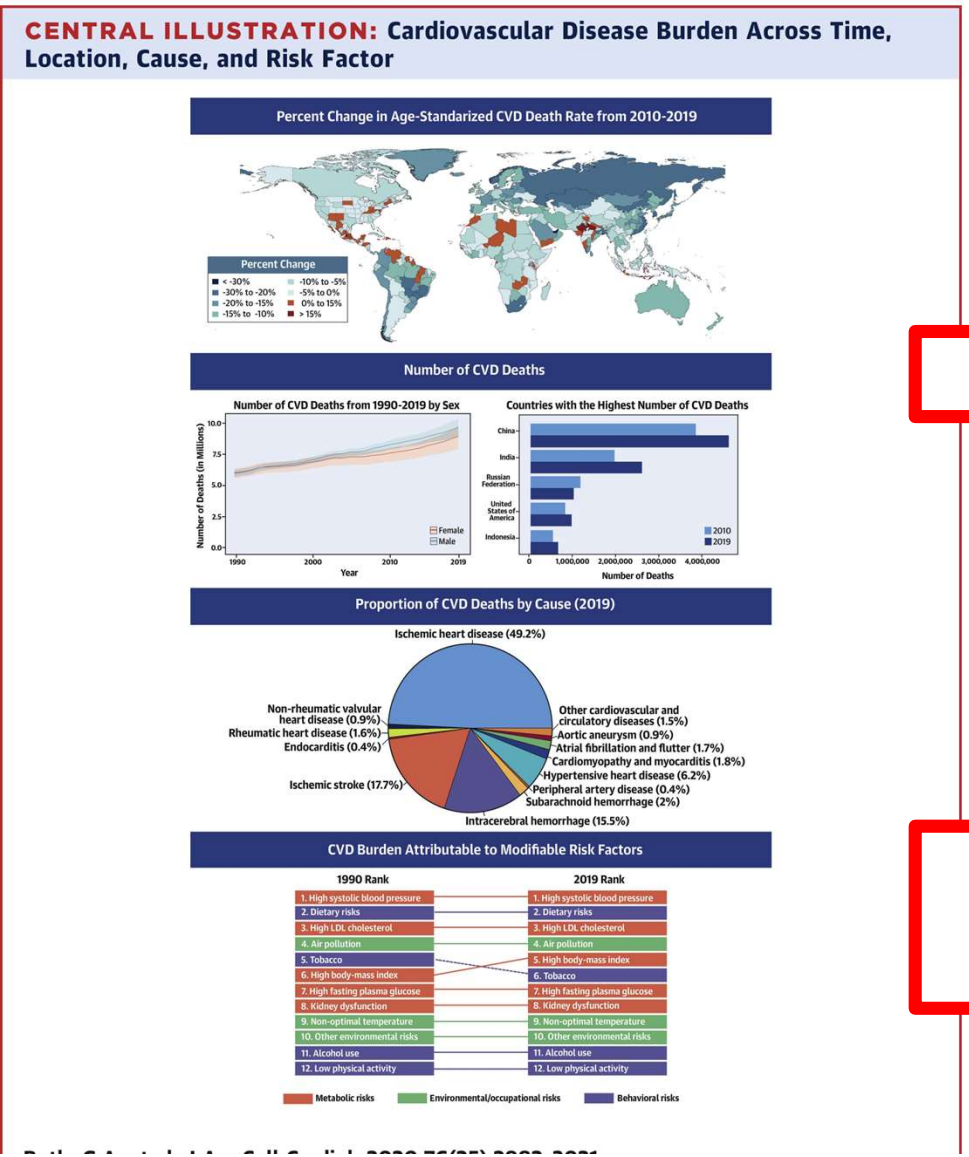

Increased Clinical Demand

Global Burden of Diseases, Injuries and Risk Factors Study 1990-2019

Roth GA, et al, JACC 2020;76:2982

- CV cases doubled to 523M
- CV deaths up 50% to 18.6M

  (COVID-19 = 1.9M in 2020)
- 48% women, 60% are 30-70 years old
- IHD accounts for ½ of cases and deaths

  (>80% from IHD + Stroke)
- DALY's up 17.7 to 34.4 million
- Death rate now rising in US and globally (Diabetes, Obesity, COVID)

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ORIGINAL INVESTIGATIONS

Cardiovascular Disease Projections in the United States Based on the 2020 Census Estimates

Reza Mohebi, MD,[a,b] Chen Chen, PhD,[a,b] Nasrien E. Ibrahim, MD,[c] Cian P. McCarthy, MB, BCh, BAO,[a,b] Hanna K. Gaggin, MD, MPH,[a,b] Daniel E. Singer, MD,[a,b,d] Emily P. Hyle, MD, MSc,[a,b] Jason H. Wasfy, MD, MPhil,[a,b] James L. Januzzi, Jr, MD[a,b,e]

ABSTRACT

BACKGROUND Understanding trends in cardiovascular (CV) risk factors and CV disease according to age, sex, race, and ethnicity is important for policy planning and public health interventions.

OBJECTIVES The goal of this study was to project the number of people with CV risk factors and disease and further explore sex, race, and ethnical disparities.

METHODS The prevalence of CV risk factors (diabetes mellitus, hypertension, dyslipidemia, and obesity) and CV disease (ischemic heart disease, heart failure, myocardial infarction, and stroke) according to age, sex, race, and ethnicity was estimated by using logistic regression models based on 2013-2018 National Health and Nutrition Examination Survey data and further combining them with 2020 U.S. Census projection counts for years 2025-2060.

RESULTS By the year 2060, compared with the year 2025, the number of people with diabetes mellitus will increase by 39.3% (39.2 million [M] to 54.6M), hypertension by 27.2% (127.8M to 162.5M), dyslipidemia by 27.5% (98.6M to 125.7M), and obesity by 18.3% (106.3M to 125.7M). Concurrently, projected prevalence will similarly increase compared with 2025 for ischemic heart disease by 31.1% (21.9M to 28.7M), heart failure by 33.0% (9.7M to 12.9M), myocardial infarction by 30.1% (12.3M to 16.0M), and stroke by 34.3% (10.8M to 14.5M). Among White individuals, the prevalence of CV risk factors and disease is projected to decrease, whereas significant increases are projected in racial and ethnic minorities.

CONCLUSIONS Large future increases in CV risk factors and CV disease prevalence are projected, disproportionately affecting racial and ethnic minorities. Future health policies and public health efforts should take these results into account to provide quality, affordable, and accessible health care. (J Am Coll Cardiol 2022;80:565-578) © 2022 by the American College of Cardiology Foundation.

Increasing Demand 2020-2060

- 2013-2018 National Health and Nutrition Examination Survey + 2020 U.S. Census Data
- 2060 Prevalence Increase:
  - IHD: 29 million persons (31%)
  - CHF: 13 million persons (33%)
  - MI: 16 million person (17%)
- Driven by DM>HTN>HLP>Obese

Increase by 1/3

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ACC Strategic Plan

Mission Statement

To transform cardiovascular care and improve heart health for all

Vision Statement

A world where science, innovation and knowledge optimize cardiovascular care and outcomes

Core Values

Patient-Centered, equity, Teamwork & Collaboration Professionalism & Excellence

GOALS	Increase relevance as the CV pro	Generate and deliver	Advance quality, equity,	Ensure organizational ability
STRATEGIES	• Provide i **value** to professionals • Engage with **Health Systems and Service Lines** • Increase **member diversity and inclusion** • Promote **clinician well-being**	• Transform how ACC knowledge is **created** • Establish a robust infrastructure to **manage** ACC knowledge and make it easily available • Transform the ACC product portfolio to utilize new infrastructure for **dissemination**	• Develop **solution sets** that integrate the **patient voice** • Enhance the **scope** and **utilization of ACC data** • Support members and engage stakeholders in the transition from a **volume to value-based payment environment**	• Expand and deliver **leadership development** curriculum • Enhance **organizational efficiency**

"all", "science", "equity"

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ACC: Transformation Toolkit

… to thrive in a changing world

- Guideline Modernization
- Registry Redesign
- Innovation
- Science/Lifelong Learning
- Workforce Development
  - Diversity, Equity, and Inclusion
  - Leadership develpoment
- Clinician Well-Being
- Advocacy

Guideline Optimization

"Clinical Guidelines" to "Clinical Guidance"

What to do How to do it Does it work?

***Guideline Optimization**:*

- *Shorter, Digital, Modular "chunks*
- *Annual updates*
- *Actionable knowledge at the "Point of Care"*

Actionable knowledge to advance CV care quality, equity, and value

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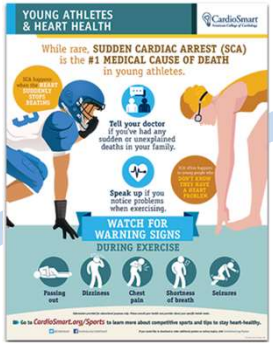
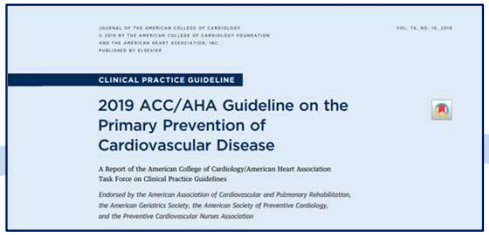
Transforming Clinical Guidance into Actionable Knowledge…



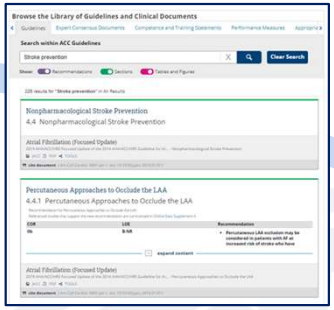
CardioSmart



ACC/AHA Guidelines

The "What"

Cardiovascular Clinical Team



Guideline-optimized search

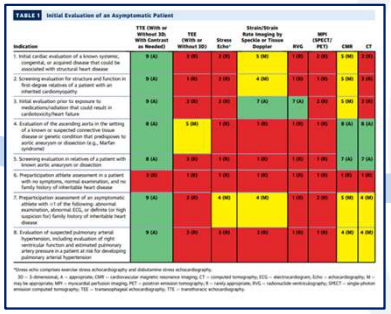
Guideline-specific solutions hub

Rapid response on ACC.org

Coded decision support

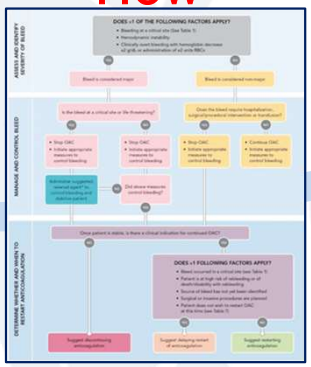
How

When



AUC

How



Expert consensus decision pathways

Clinical apps

Where (bedside)

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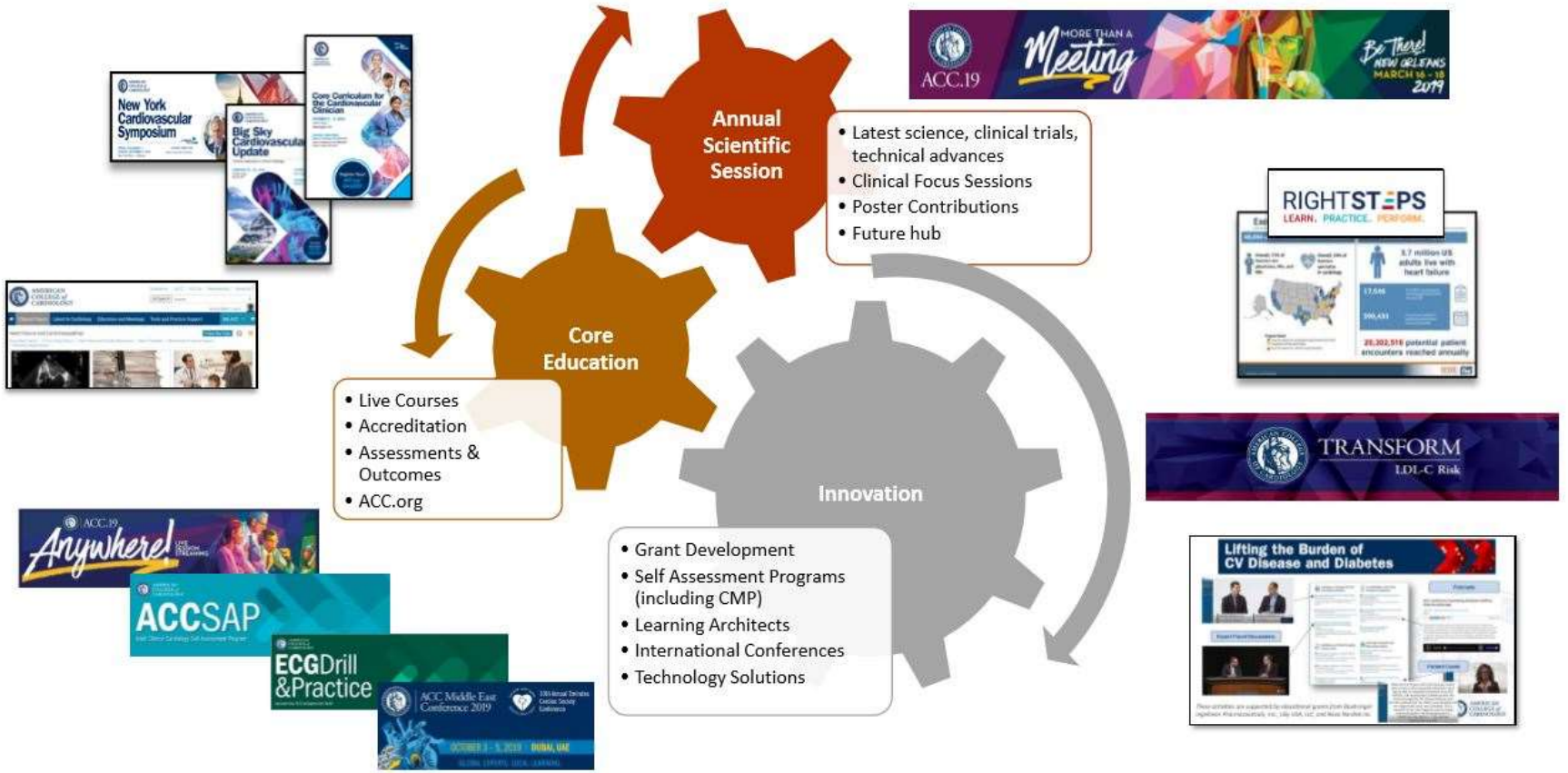
Lifelong Learning: Actionable Knowledge

ACC: Science and Learning organization



Why Registries? "The language of quality improvement"

NCDR®
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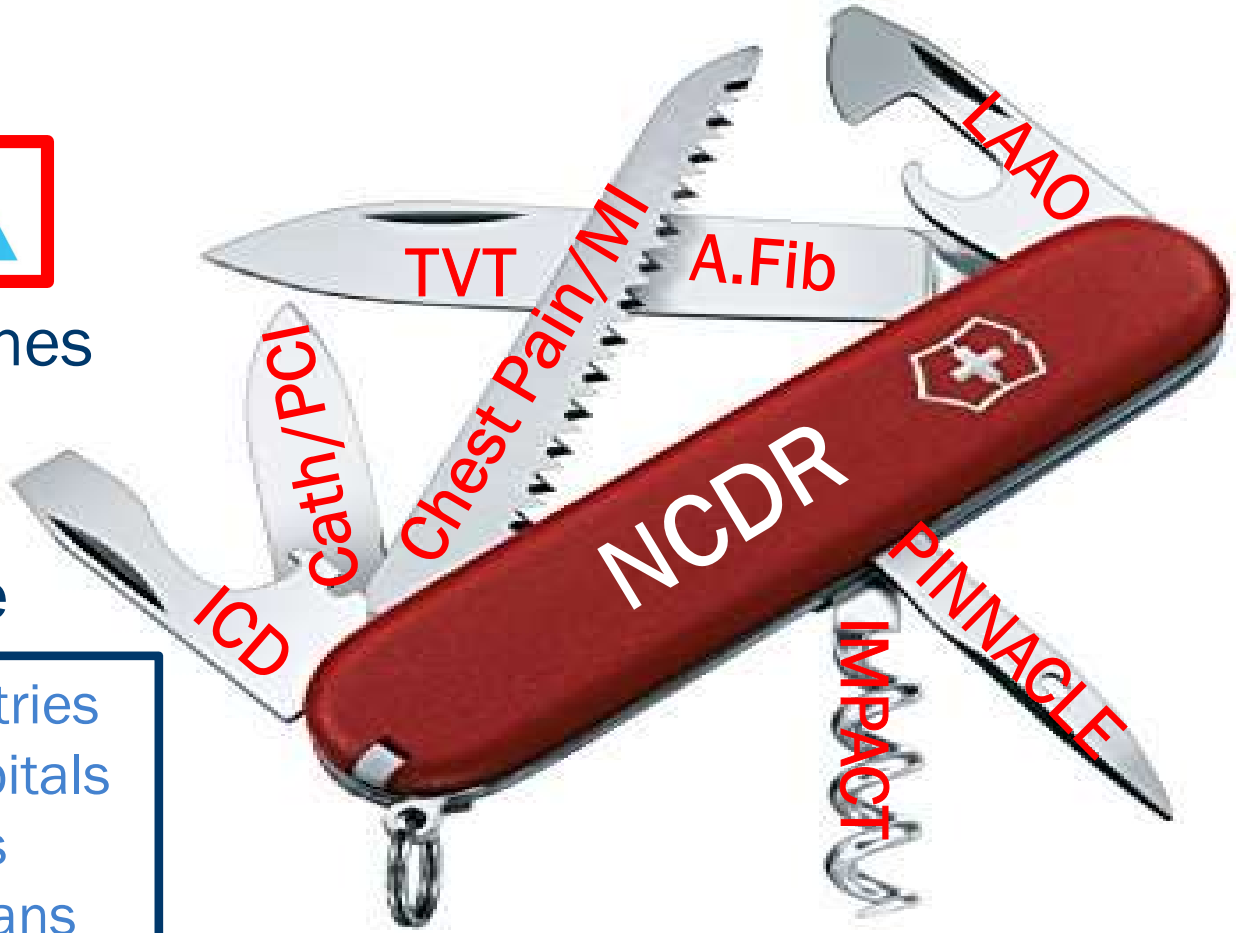
25 YEARS TRANSFORMING DATA INTO CLINICAL PRACTICE

- Drive Guidelines
- Research
- Accreditation
- Quality/Value



10 Clinical Registries
>2500 U.S. Hospitals
29 Int'l Programs
>40,000 Physicians
>95 million records

Innovation?

1962 ---------- 2022

Out Patient Care - then

Out Patient Care - now

Courtesy of John Rumsfeld, MD, PhD, FACC

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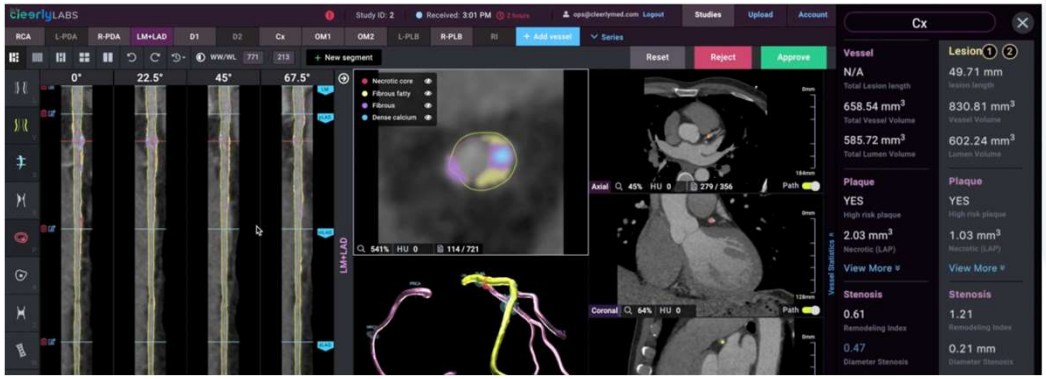
Burdens/CV Workforce: Innovation



ACC Innovation Program

Digital Health Strategy

- AI = "Collaborative Intelligence"
- Robotics
- Remote Monitoring
- Virtual Care/Telehealth
- Predicitve Analytics
- Clinical Decision Support
- Implementation Science

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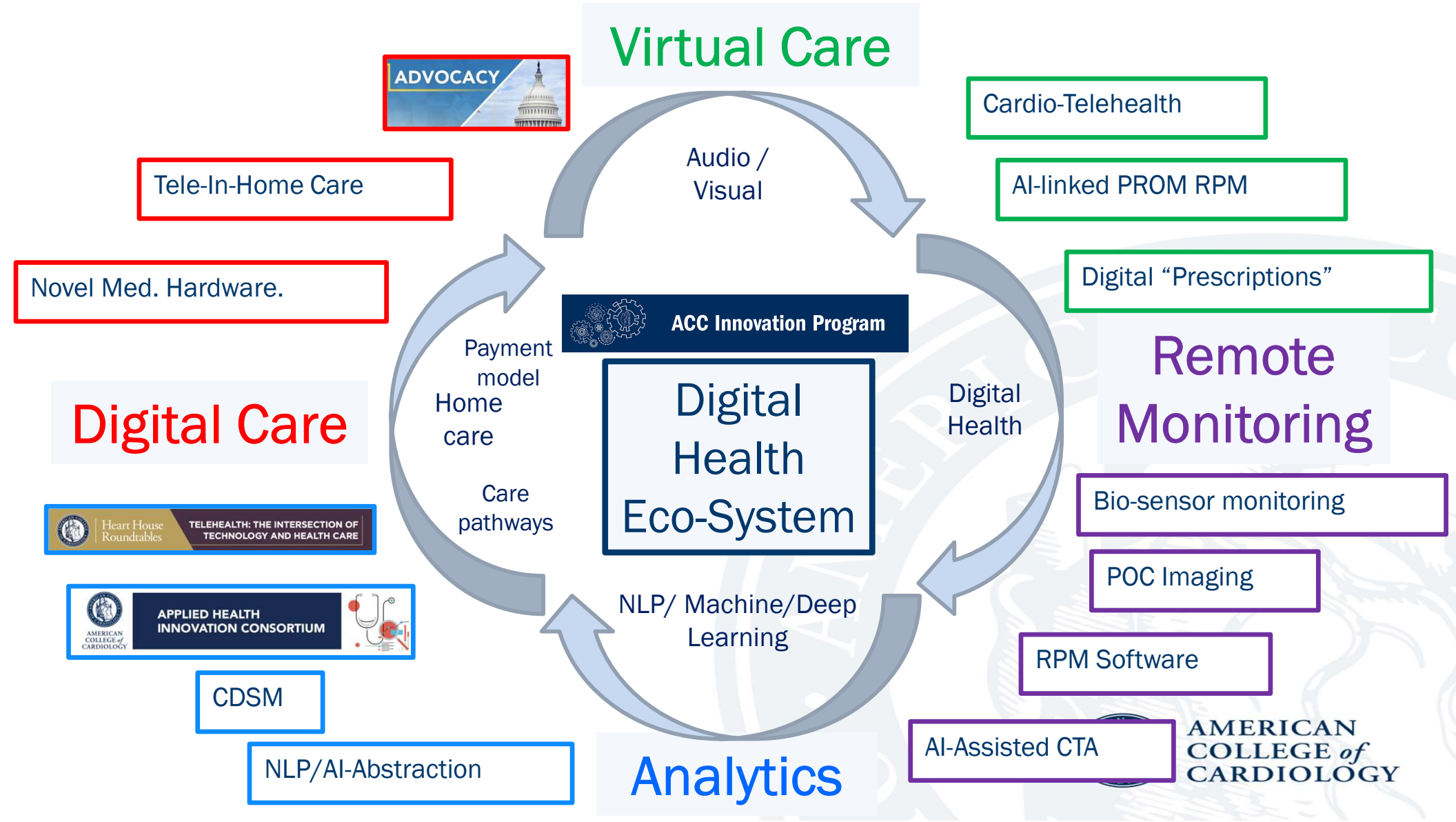
Virtual Care
ADVOCACY
Cardio-Telehealth
Tele-In-Home Care
AI-linked PROM RPM
Audio / Visual
Novel Med. Hardware.
Digital "Prescriptions"
ACC Innovation Program
Payment model
Home care
Digital Health Eco-System
Digital Health
Remote Monitoring
Digital Care
Care pathways
Bio-sensor monitoring
Heart House Roundtables
TELEHEALTH: THE INTERSECTION OF TECHNOLOGY AND HEALTH CARE
POC Imaging
APPLIED HEALTH INNOVATION CONSORTIUM
NLP/ Machine/Deep Learning
RPM Software
CDSM
AI-Assisted CTA
NLP/AI-Abstraction
Analytics
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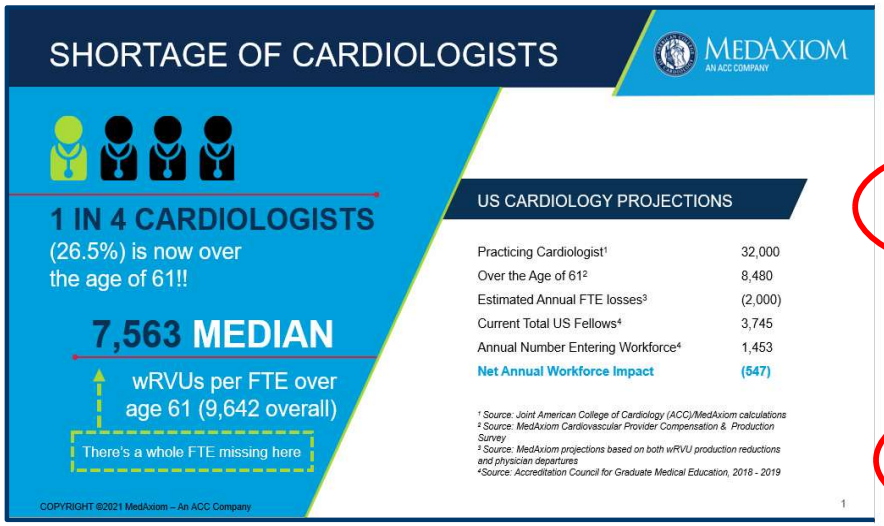
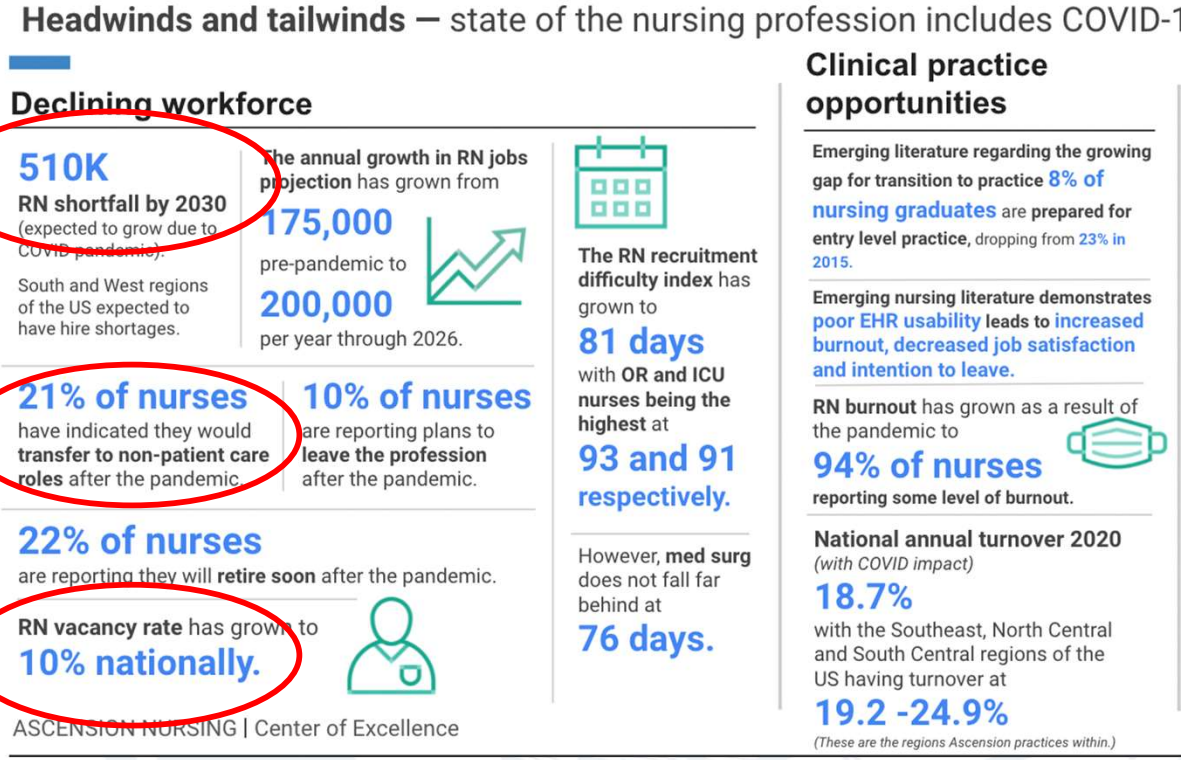
Clinical Workforce Crisis



Losing >500 cardiologists/yr
>5000 in next decade

MedAxiom 2022 Physician Survey
AAMC. "Complexities of Physician Supply and Demand: Projections from 2019 to 2034. June 2021



Drivers: Aging, Burnout, Deferred Retirement

Solutions: GME, Care Redesign, Innovation

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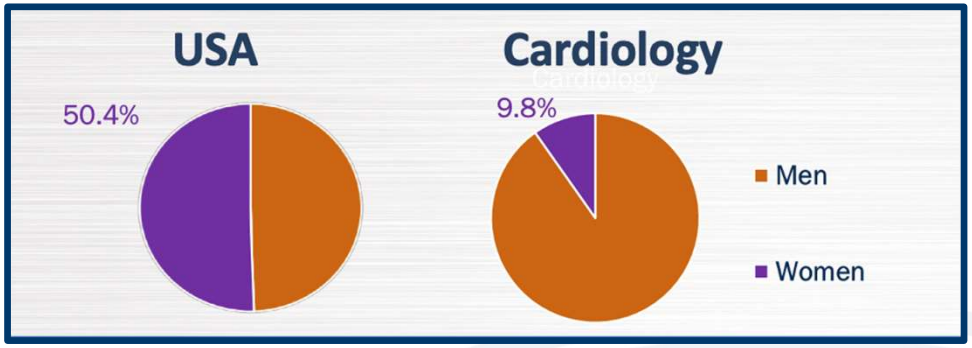
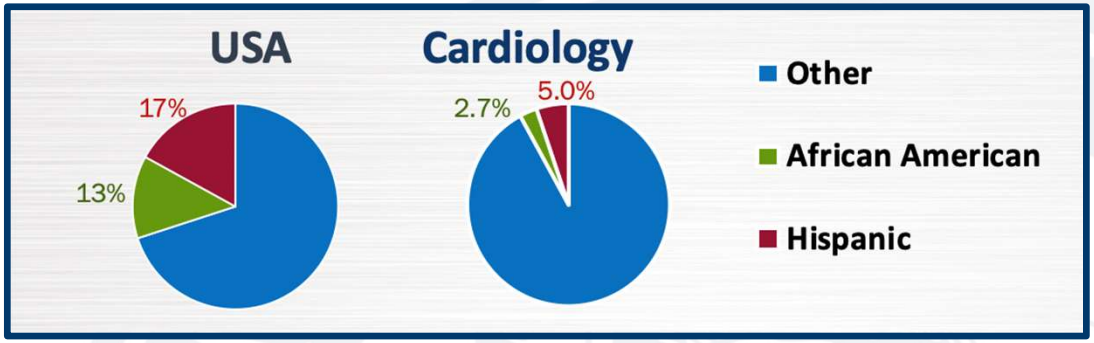
Cardiology:

Do We Reflect the Communities We Serve?





Challenges:

- ACGME CV Training Programs:
  - 4% Non-Hispanic Black
    - (3% Black Faculty)
  - 6% Hispanic
- Women in Cardiology = 10% in practice (fewer in EP and IC)
  - 50% in Med School
  - 37% in IM
  - 26% new FACC's
  - 32% female fellowship applicants 2022

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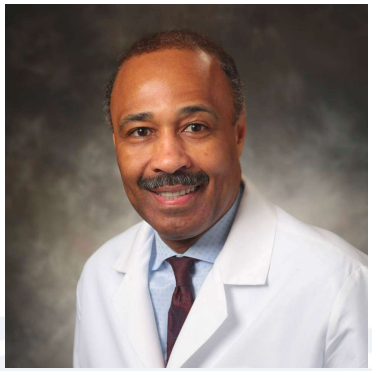
American College of Cardiology Diversity and Inclusion Initiative

ACC's DE&I Focus:

Melvin Echols, MD, FACC
ACC Chief Diversity Officer

Pam Douglas, MD, MACC
Founder, ACC D&I Sect.



Paul Douglas, MD, MACC
Chair, ACC Equity Task Force

- ✓ Implicit Bias Training
- ✓ Young Scholars Program – High Schools
- ✓ URM and Female IM Residents Program
- ✓ Grow pipeline, promote diversity in leaders and faculty
- ✓ Women's Mid-Career Leadership Institute
- ✓ Emerging Leaders Academy
- ✓ Leadership Forum Series

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Building an Environment of Professionalism: Necessary to ensure CWB

Clinician burnout 2X since COVID

- Optimized Work Environment
  - Eliminate burdens,
- Culture of Professionalism
  - Engagement, respect, leadership
- Self-Resilience, Self-Leadership
  - Empathy, balance, remove stigma's

Mission:
To transform CV care to improve heart health for ALL

- Clinical Guidance
- Lifelong Learning
- Clinical Registries
- Innovation
- Workforce/Professionalism
- Well-being
- Advocacy

Questions?

Thank you for listening

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Advocacy Update
December 2022

Nick Morse, MBA

Division Vice President, Advocacy

American College of Cardiology

The Big Picture: It's rough out there.

- Clinician frustration
- Looming cuts
- Fractious environment
- Immense, competing priorities
- Lengthy lame duck to-do list
- Narrow majorities next Congress

Fall 2022 ACC Talking Points

- **Increasing Patient Access to Care**
  - Address pending cuts and seek long-term solutions
    - MPFS conversion factor, PAYGO
    - Cardiac ablation services
    - Pivot toward systemic reform
      - AMA + congressional champions
      - Role of ACC, others
  - **Expand patient access to CV rehab**
- **Improving Clinician Well-being**
  - Streamline prior authorization
  - Address workplace violence
- **Developing Public Health Initiatives**
  - South Asian Heart Health Awareness and Research Act (SAHHARA)
  - Valvular heart disease research and awareness (CAROL)

Health Equity: Finding Opportunities

- ACC HETF: Setting the course
- View all policy issues through the equity lens
- Identify and engage willing partners
  - Stakeholder groups
  - Congress
  - CMS
  - CMMI
- RFI responses
- ACC MDUFA testimony
- SAHHARA
- Postpartum Medicaid coverage
- PAD
- Incorporation of HE themes within advocacy communications

Noteworthy Recent Developments

- 2023 MPFS released
  - Ablation cuts mitigated
  - Conversion factor reduction
  - Split/shared visits policy, AUC delayed
  - Updates to quality programs, including adjustments to promote health equity
  - Advancing Care for Heart Disease MVP expanded
- ACC Value Based Care Forum focused on cv-specific examples of accountable care
- CAROL Act
- Proposed rule to improve prior authorization (includes social risk factor data RFI)
- Data Mapping to Save Moms' Lives Act

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ACC's Health Equity Strategy

Industry Advisory Forum
December 8, 2022

Paul L Douglass, MD, MACC

Health Equity Task Force

- **Dipti Itchhaporia, MD, FACC (Chair)**
- **Paul Douglass, MD, MACC (Vice Chair)**
- **Kathryn L. Berlacher, MD, FACC**
- **Biykem Bozkurt, MD, FACC**
- **Prabhakaran Dorairaj, MD,**
- **Pamela S. Douglas, MD, MACC**
- **Linda D. Gillam, MD, MACC**
- **Akshay K. Khandelwal, MD, FACC**
- **Robert Roswell, MD, FACC**
- **Herman A. Taylor, Jr., MD, FACC**
- **Thad F. Waites, MD, MACC**
- **Marlene S. Williams, MD, FACC**
- **Staff: Brendan Mullen, Janice Sibley, Nick Morse, Maghee Disch and Akua Asare, Christine Chance and Rachel Devaux-Jeffries**

Roles and Responsibilities:
Identify principles and recommend strategy related to ACC's role to address racism and social justice via health equity, focusing in the five following areas:

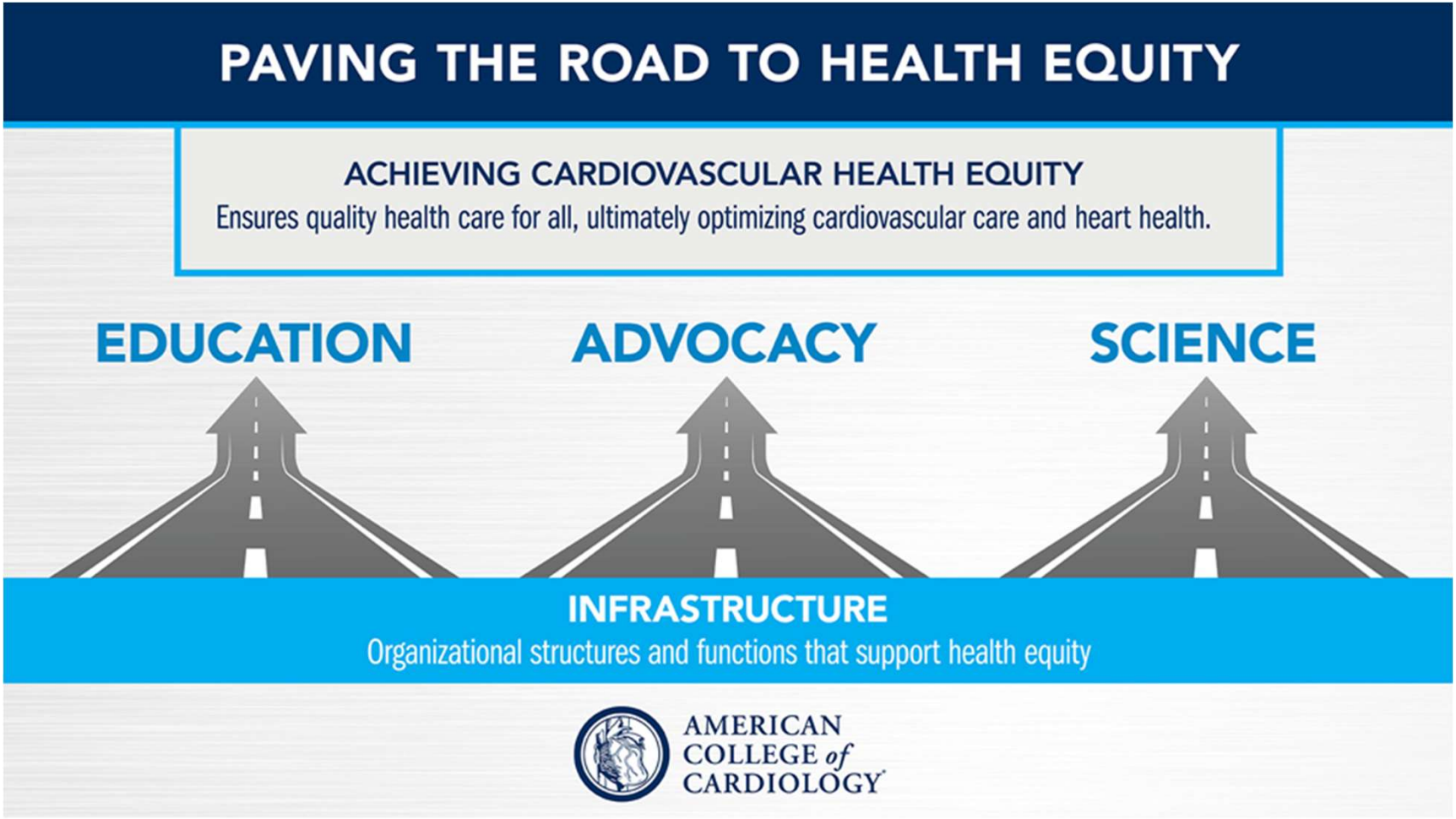
Improving access to care for underserved patients and populations

Reducing system and structure barriers which cause health disparities

Addressing social economic determinants of health

Leveraging medicine's established tools for broad change (such as education and public policy) and emerging new social technologies

Building partnerships with effective leadership organizations such as the Association of Black Cardiologists and the American Board of Internal Medicine.


PAVING THE ROAD TO HEALTH EQUITY
ACHIEVING CARDIOVASCULAR HEALTH EQUITY
Ensures quality health care for all, ultimately optimizing cardiovascular care and heart health.
EDUCATION
ADVOCACY
SCIENCE
INFRASTRUCTURE
Organizational structures and functions that support health equity
AMERICAN COLLEGE of CARDIOLOGY

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
VOL. 77, NO. 20, 2021

PUBLISHED BY ELSEVIER

LEADERSHIP PAGE

Paving the Way for Health Equity in Cardiology

Why Does it Matter?

Dipti Itchhaporia, MD, FACC, *President, American College of Cardiology*

I have been impressed with the urgency of doing. Knowing is not enough; we must apply. Being willing is not enough; we must do.
–Leonardo da Vinci (1)

Health equity has long been an ideal. It is rooted in medicine going back into the mid-nineteenth century when it was recognized that social and class inequalities lead to health inequalities. The core of health equity is the intention to eliminate unfair and avoidable differences in disadvantaged groups that have poorer survival rates, life conditions, and health status that perpetuate their disadvantages. In spite of the fact that many organizations have pursued the ideal, this has not translated into equitable and healthy societies.

The coronavirus disease 2019 (COVID-19) pandemic

What is known is that social determinants of health—the conditions in which people are born, grow, live, work, and age—have significant impact on health, quality of life, and health care costs. Conditions such as economic stability, physical environment, education, food, and access to care also support or inhibit our health (Figure 1). There is evidence that determinants of health are interlinked with class, ethnicity, gender, education level, as well as social vulnerabilities.

In the United States, recent data from the Centers for Disease Control and Prevention (CDC) have shown that Blacks, Latinx, and Asians have substantially higher rates of infection, hospitalization, and death from COVID-19 compared with Whites (4). Vaccine and testing rates are also lower in these populations,

JACC Leadership Page on Health Equity, May 2021

ACC HEALTH EQUITY STRATEGY

VISION

Achieve a culture of health where every person reaches their full cardiovascular health potential as a natural right.

GOALS	CREATE A CULTURE OF HEALTH EQUITY IN CARDIOVASCULAR MEDICINE	PRIORITIZE HEALTH EQUITY IN ALL ACC ACTIVITIES	ELIMINATE DISPARITIES BY ENSURING EQUITABLE CARDIOVASCULAR CARE FOR ALL
STRATEGIES	• Execute change management to create a mindset that health equity is an essential component of quality cardiovascular care • Commit to cardiovascular health equity principles and develop policies for action • Support and pursue partnerships with organizations committed to addressing health equity	• Embed health equity in educational curriculum and programming and guidelines development • Provide clinical programs and guidance to identify and evaluate disparities and social determinants of health • Integrate health equity into compliance requirements	• Provide actionable data and tools that empower cardiovascular professionals to address health disparities and social determinants of health • Partner with public health and community stakeholders to ensure availability of resources for optimal patient care that eliminates disparities • Drive innovation to address health equity

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Timeline of Key ACC Health Equity Activities

May 2020 - BOT Health Equity Task Force Formed

Current State Assessment

- Reviewed survey results
- Identified what ACC could do considering our strengths
- Developed definitions

Execution Planning

- Identify health equity priorities
- Develop the Implementation Plan
- Secure resources / budget

Q3 2020 – Q1 2021

DEFINITIONS

credo

Reviewed 2008 and 2011 surveys

CardioSurve – March 2021
(FACCs, FIT, CVT)

Q1 – Q2 2021

ACC Health Equity Strategy

- Mission, Vision and 3 Goals
- High-level Strategies
- Metrics

Q3 2021 – 2022

Dec 2021
ACC Industry Advisory Forum
Focus: Health Equity

Nov 2021
Staff Strategy Session

- Work already underway
- Opportunities to pursue
- Identified impactful activities for 2022-23

2022
Key Activities/Deliverables

- Inventory internal/external stakeholders' efforts
- Stakeholders' Summit
- Implementation Roadmap
- Integrate health equity into ACC's next Strategic Plan

JACC Journals **Leadership Page Articles by Dr. Dipti Itchhaporia**

- *Paving the Way for Health Equity in Cardiology: Why Does it Matter?* (May 2021)
- *Population Health: Intersecting Technology, Data, Health Equity to Achieve Health Care Transformation* (Oct 2021)
- *The Evolution of the Quintuple Aim: Health Equity, Health Outcomes, and the Economy* (Nov 2021)

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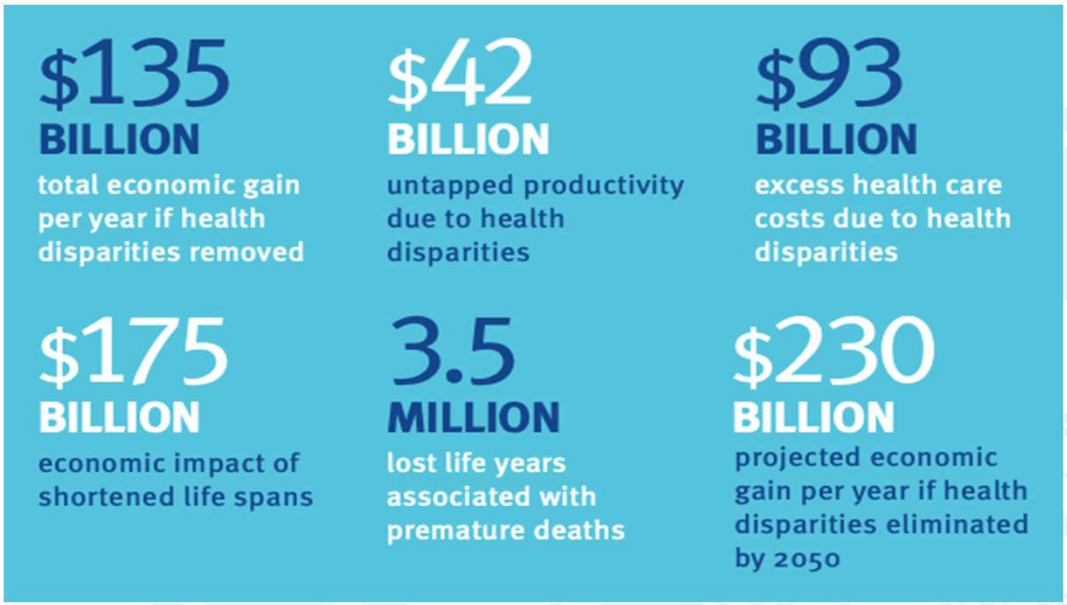
Science without conscience is the soul's perdition.

~ Francois Rabelais

The Business Case for Health Equity

-Health disparities are costly and there would be a positive economic impact if health equity is better implemented

-It has been estimated by the Institute of Healthcare Improvement, that health inequities cost the United States $83 billion and this is anticipated to grow to $300 billion by the year 2050



https://altarum.org/sites/default/files/uploaded-publication-files/WKKellogg_Business-Case-Racial-Equity_National-Report_2018.pdf
https://cmelearning.com/resources/the-case-for-health-equity/#business
https://www.astho.org/Programs/Health-Equity/Economic-Case-Issue-Brief/
https://link.springer.com/article/10.1007/s11606-016-3604-7
•https://www.commonwealthfund.org/blog/2021/any-medicare-solvency-effort-must-include-advancing-health-equity

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Why Social Determinants of Health Matters

70% Patient's health outcomes impacted by social and behavioral factors

17% Patients unable to visit their doctor due to unreliable transportation

21% Patients who need to prioritize rent over doctor's appointments & medication

Socioeconomic inequalities have **worsened racial health care disparities** In the past 20 years.

Compounding social barriers	**Impact on patient outcomes**
Transportation	Missed appointments
Food insecurity	More severe toxicities
Housing instability	Treatment non-adherence
Social isolation	Poorer outcomes

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Advancing Heart Care Worldwide

Siegel RL, Miller KD, Jemal A. Cancer statistics, 2019. *CA Cancer J Clin* 2019;**69**:7-34.
Hood CM, Gennuso KP, Swain GR, Catlin BB. County Health Rankings: Relationships Between Determinant Factors and Health Outcomes. *American Journal of Preventative Medicine.* 2016; **50**(2):129-135.

ACC Strategic Plan

Mission Statement	Vision Statement	Core Values
To transform cardiovascular care and improve heart health	A world where innovation and knowledge optimize cardiovascular care and outcomes	Patient-Centered Teamwork & Collaboration Professionalism & Excellence

GOALS	STRATEGIES
Increase relevance as the CV professional home	• Provide **indispensable value** to CV professionals • Engage with **Health Systems and Service Lines** • Increase **member diversity and inclusion** • Promote **clinician wellbeing**
Generate and deliver actionable knowledge	• **Discover** user needs and **envision** the future product portfolio • Transform how ACC knowledge is **created** • Establish a robust infrastructure to **manage** ACC knowledge and make it easily available • Transform the ACC product portfolio to utilize new infrastructure for **dissemination**
Advance quality, equity, and value of CV care	• Develop **partnerships** to deliver standards and support solutions • Develop **solution sets** that integrate the **patient voice** • Enhance the **scope** and **utilization of ACC data** • Support members and engage stakeholders in the transition from a **volume to value-based payment environment**
Ensure organizational growth and sustainability	• Create **innovative projects to drive the mission** of ACC • Expand and deliver **leadership development** curriculum • Enhance **organizational efficiency**

Health Equity Alignment to ACC Strategic Priorities

Crosswalk based on alignment to the Health Equity Strategic Metrics

Ensuring broad access and providing enabling tools is a strong health equity theme across all areas.

Health Equity Strategic Goals		Create a Culture of Health Equity in Cardiovascular Medicine	Prioritize Health Equity in all ACC Activities	Eliminate Disparities by Ensuring Equitable CV Care for All
		Mindset, Principles and Policies; Partnerships that Address Health Equity	*Education, Clinical Guidance, Compliance Requirements, etc.*	*Actionable Data and Tools for Clinicians and Patients; Access*
2022 Strategic Priorities	Digital Transformation	• **Support and enable generation, dissemination, and access to health equity tools and data** • **Assess the role and adequacy of telehealth, remote monitoring, AI, and digital learning health systems to achieve health equity**		
	NCDR Optimization	• Health equity training to change mindset and on policies (100% compliance) • Increase joint sponsorships with partner organizations to pursue advocacy and academic endeavors centered around health equity	• **Embed health equity in ALL quality improvement programs (e.g., NCDR registries & reports, Accreditation, guidance, etc.)**	• Educational modules for clinicians (data source)
	Clinical Guidance / Guideline Optimization	• ACC policies adopt health equity objectives and language	• LLOC embeds health equity in ALL the educational curriculum • Advocate for addition of health equity in blueprint of ABIM/CMP assessments and questions	• **All guidelines and tools to address implications of disparities and SDoH** • Monitor CV Care Deserts (ensuring access)
	Global Acceleration Strategy	• Partnerships that support and promote global health equity (NCD Academy, World Heart Federation, etc.)		

Portfolio Elements of ACC Diversity, Equity, and Inclusion Division

“Tuskegee Study of Untreated Syphilis in the Negro Male”
1932 – US Public Health Service

600 Black men, 399 with syphilis, 201 without syphilis
No informed consent
Treated for "Bad Blood"
Free Meals, Free Medical Exams, and Burial Insurance

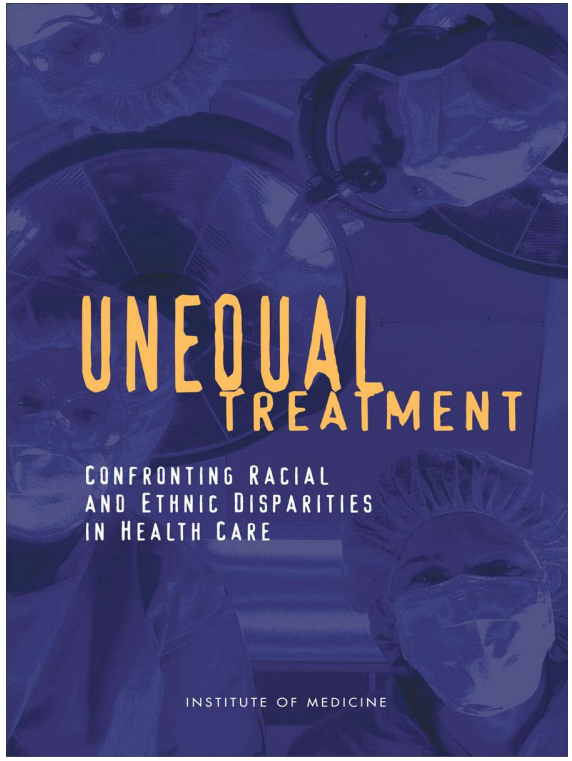
"Tuskegee Study of Untreated Syphilis in the Negro Male"
1932 – US Public Health Service

40 year study
1947 Penicillin drug of choice
1972 Associated Press Story
1972 Study Terminated

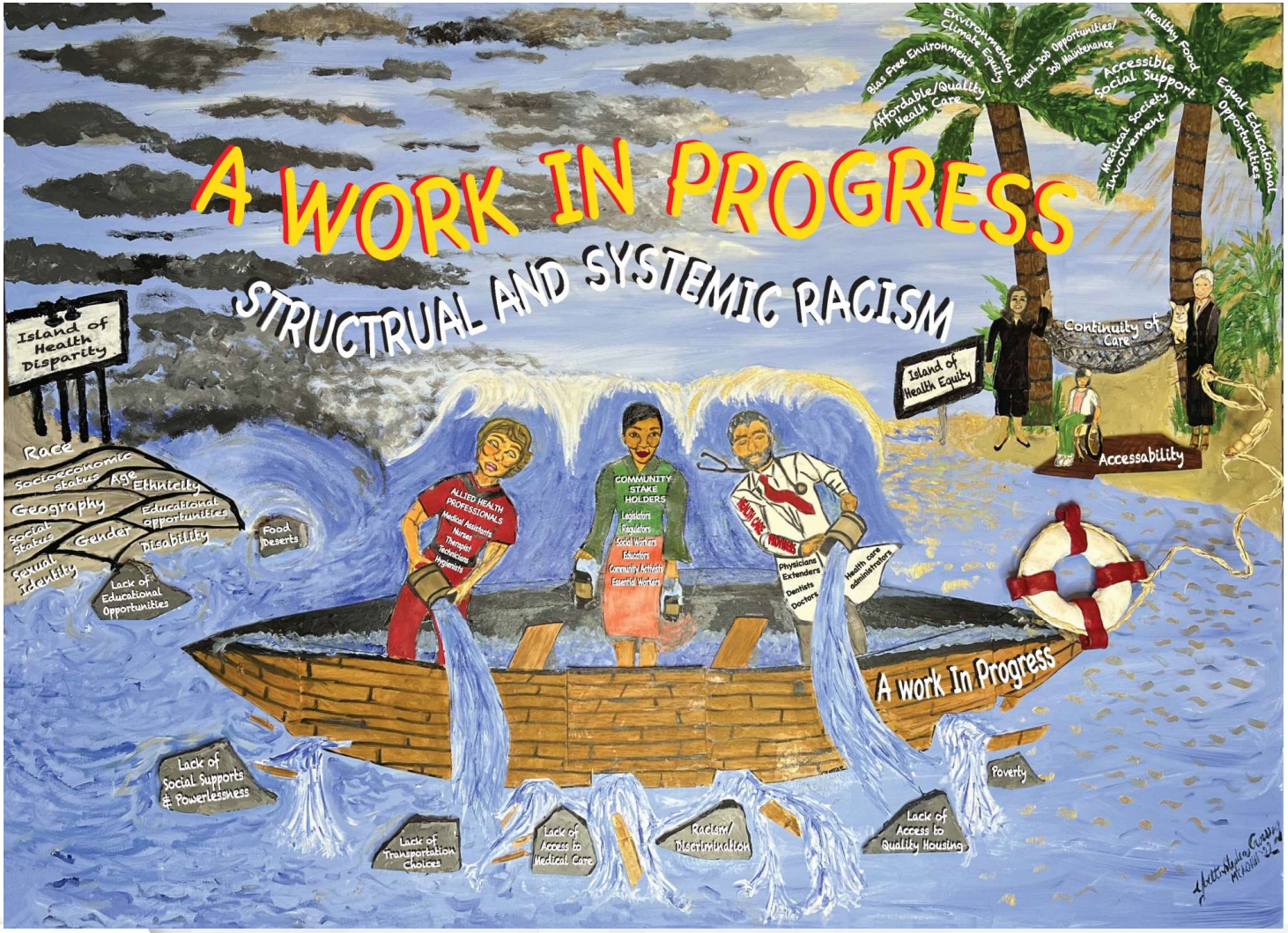
IOM Report, 2002: Assessing the Quality of Minority Health Care

"Disparities in the health care delivered to racial and ethnic minorities are real and are associated with worse outcomes in many cases, which is unacceptable."

-- Alan Nelson, retired physician, former president of the American Medical Association and chair of the committee that wrote the Institute of Medicine report, *Unequal Treatment: Confronting Racial and Disparities in Health Care*



Structural and Systemic


A WORK IN PROGRESS
STRUCTRUAL AND SYSTEMIC RACISM
Island of Health Disparity
Race
Socioeconomic status
Age
Ethnicity
Geography
Educational opportunities
Social Status
Gender
Disability
Sexual Identity
Food Deserts
Lack of Educational Opportunities
Environmental Climate Equity
Bias Free Environments
Affordable/Quality Health Care
Equal Job Opportunities/ Job Maintenance
Accessible Social Support
Healthy Food
Equal Educational Opportunities
Medical Society Involvement
Island of Health Equity
Continuity of Care
Accessability
ALLIED HEALTH PROFESSIONALS
Medical Assistants
Nurses
Therapist
Technicians
Hygienists
COMMUNITY STAKE HOLDERS
Legislators
Regulators
Social Workers
Educators
Community Activists
Essential Workers
HEALTH CARE PROVIDERS
Physicians Extenders
Dentists
Doctors
Health care administrators
A work In Progress
Lack of Social Supports & Powerlessness
Lack of Transportation Choices
Lack of Access to Medical Care
Racism/ Discrimination
Lack of Access to Quality Housing
Poverty

Coffee Break

Panelists please come to front of room

All return to room in 5 mins.

ACC Experience in Diverse Investigator Training

Clinical Trials Research: Upping Your Game

Mary Norine Walsh, MD, MACC

Industry Advisory Forum –
December 8, 2022

Goal: Address Problems and Implement Solutions in Clinical Trials Research

Problems

- Too few women and Under-Represented Cardiologists (URCs) in clinical research leadership
- Negative implications: Lack of diversity of thought, participation and leadership
- Limits access to talent and lack of opportunity for women/URC investigators

Solutions

- Increasing the diversity of clinical trials researchers will improve science and enhance innovation
- Adding underrepresented women and racial/ethnic minority scientists and empowering them will increase the talent pool
- Attention to diversity across clinical research leadership, design, and execution will improve the evidence base and enhance patient diversity and outcomes

Diversity matters to ACC

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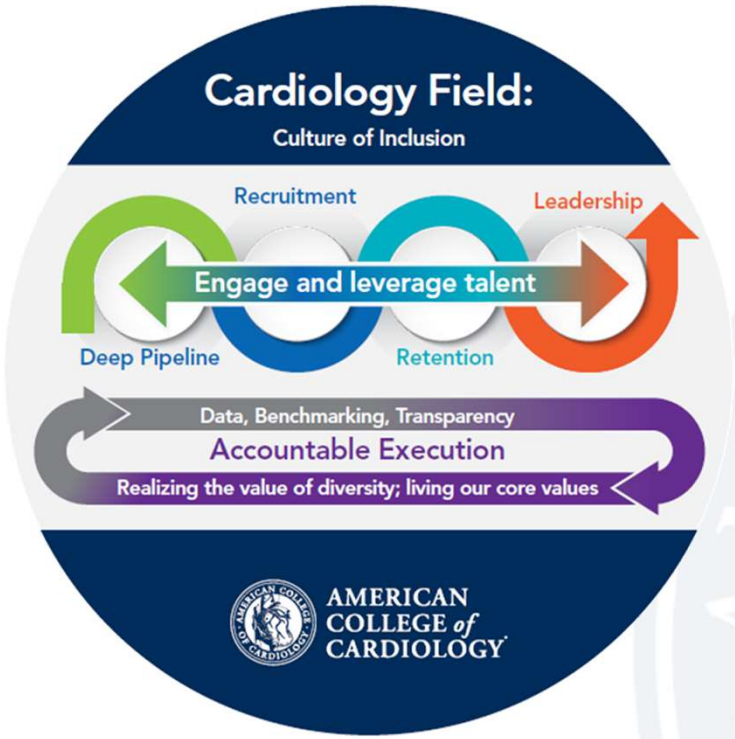
The CTR Program is Part of the ACC Diversity, Equity and Inclusion Initiative



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CTR Program Objectives

- Develop clinical trial research leaders of the future
  - Research knowledge and skills
  - Personal leadership development
  - Exposure to senior leaders/faculty
- Enhance diversity and inclusivity of future research leaders
- Foster mentoring and peer mentoring networks
- Improve cardiovascular clinical science

We Are Diverse: CTR Cohorts

	CTR 1.0	CTR 2.0	CTR 3.0	Totals
	2019	2020-2021	2022	
Total Learners	**45**	**48**	**49**	**142**
Women	45 (100%)	25 (52%)	27 (56%)	97 (68%)
Race ethnicity				
White	24 (53%)	13 (27%)	13 (27%)	50 (35%)
Asian	17 (34%)	16 (33%)	21 (45%)	54 (38%)
URC total	4 (8%)	17 (34%)	13 (27%)	34 (24%)
Black	2 (4%)	11 (23%)	4 (8%)	17 (12%)
Hispanic	2 (4%)	6 (12%)	8 (15%)	15 (11%)
Indigenous	Na	Na	1 (2%)	1
Other			2(4%)	1
International	3 (6%)	3 (6%)	5 (10%)	11 (8%)

CTR Curriculum Topics

In-person & virtual sessions, webinars, workshops, breakouts, panels and career development exercises

- Budget and Finance
- Clinical research operations
- Career Development
- CTR Career Mapping
- CTR Research Proposal
- CTR Executive Coaching
- Funding Resources
- Emerging trends in research
- Health Equity Research
- Leadership Development
- Networking with CTR Faculty
- Networking with CTR Learners
- Regulatory Considerations
- Research methods
- Role of Diversity in Clinical Trial Research
- Role of Research Team Members
- Preparing Publications for Research
- Statistics and Quantitative Skills
- Trial design

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Steering Committee – All Cohorts

- Wayne Batchelor, MD, FACC – Inova Heart & Vascular
- LaPrincess Brewer, MD, MPH, FACC - Mayo Clinic
- Anne B. Curtis, MD, FACC - University of Buffalo
- Pamela Douglas, MD, MACC - Duke University
- Claire Duvernoy, MD, FACC – University of Michigan
- Eldrin Lewis, MD, MPH, FACC – Stanford University
- Roxana Mehran, MD, FACC - Mt. Sinai
- Selma Mohammed, MBBS, FACC – Creighton University

- Puja Parikh, MD, MPH, FACC - Stonybrook
- Gail Pearson, MD, FACC - National Institutes of Health
- Robert O. Roswell, MD, FACC – Northwell
- Jorge Saucedo, MD, FACC – University of Wisconsin
- Shashank Sinha, MD, FACC - Inova Heart & Vascular
- Kevin Thomas, MD, FACC – Duke University
- Mary Norine Walsh, MD, MACC - St. Vincent Heart Center
- Tracy Wang, MD, MHS, MSc, FACC - PCORI
- Karol Watson, MD, PhD, FACC - UCLA

Leadership Development: Clinical Trials Research

- First cohort held May 2019
- 45 women cardiologists completed first program
- Expanded CTR program
- Expanded to a one-year curriculum to include three two-day programs and a series of online webinars
- 45-49 per cohort
- CTR 2.0 (2020 – 2021) was the most diverse cohort selected for an ACC leadership program to date
- Launched CTR 3.0 in January 2022 – concluded November 2022
- Actively seeking for funding for CTR 4.0 and beyond

Clinical Trials Research Program Format

- Three in-person sessions (two-day)
- Breakouts, plenary sessions, leadership development exercises, networking reception and dinner
- Plenaries have 2-3 short talks and >= 20 min panel
- Very interactive
- Webinars (also recorded and posted on-line)
- Pre-session recordings (learners can access at own pace)
- In-person reception (at ACC.xx, including ACC.22)
- Online private CTR group on ACC's Member Hub for discussion, posting resources, and networking
- Ongoing learner-directed accountability groups

CTR Program/Speaker Highlights

Program Sessions

- Diversity and Inclusion in Clinical Trials Research
  - Barbara Bierer, MD & Karol Watson, MD, PhD, FACC
- Embedding Diversity and Equity in Clinical Research
  - Melvin Echols, MD, Eldrin Lewis, MD, Jennifer Mieres, MD. Gail Pearson, MD, and Robert Roswell, MD
- Future of Clinical Trials
  - Raina Merchant, MD, MSHP & Gail Pearson, MD, ScD (NIH)
- Fireside Chat with FDA
  - Norman Stockbridge, MD & Bram Zuckerman, MD
- How to Publish
  - Panel: Five editors in chief of cardiology journal
- Identifying and Refining Research Questions
  - Kevin Thomas, MD
- Professional development
  - Career Action Plan
- Research Methods and Statistics
  - Adrian Coles, PhD & Kevin Anstrom, PhD

Webinars

- Clinical Trials Research: Influencing Others
- How to Get Admitted to the Exclusive Club of Research Leadership
- Open House with NIH Experts (Webinar)
- Research Proposal Workshop Webinar Series

Research Proposal Competition

- (New) Two cycles of CTR learners invited to submit research proposals
- Evaluated and scored by ACC's Research Fellowship Awards Committee
- Ten learners total awarded $20,000 for one-year research projects

CTR Research Awardees
2020 – 2021 Cohort

Paulino Alvarez, MD
Cerebral Blood Flow, Autoregulation, and Compliance in Decompensated Heart Failure with Reduced Ejection Fraction

Jun Hua Chong, MBBS, FRACP
The EMPA-Trastuzumab Trial: The Use of EMPAgliflozin to Prevent Trastuzumab-induced Left Ventricular Dysfunction Trial

George Ephrem, MD, FACC
Sacubitril/Valsartan Outcomes in Adult Congenital Heart Disease Patients With a Systemic Right Ventricle

Anastasia Shchendrygina MD, PhD
Colchicine in Patients With Heart Failure and Preserved Left Ventricular Ejection Fraction

Jill Steiner MD, MS, FACC
Assessing Social Determinants of Health as Related to Resilience in Adults with Congenital Heart Disease

CTR Research Awardees
2022 Cohort

Zain Ul Abideen Asad, MD, MS, FACC
Screening for Atrial Fibrillation in Patients with Cancer: A Pilot Randomized Controlled Clinical Trial

Andrea Elliott, MD, FACC
Mild hypothermia versus a fever avoidance strategy in cardiac arrest patient rescued with extracorporeal cardiopulmonary resuscitation

Abhishek Khemka, MD, FACC
Cardiometabolic Risk in African American Patients with Prostate Cancer

Estefania Oliveros, MD, FACC
Factors Affecting Ventilatory Inefficiency and Oxygen Limitations in Chronic Thromboembolic Disease with the Use of Cardiopulmonary Exercise Testing in an Outpatient Office Visit

Nosheen Reza, MD, FACC
Optimal Management of Background Therapy in Patients with Symptomatic Obstructive Hypertrophic Cardiomyopathy Initiated on Mavacamten, a Novel Myosin Inhibitor

Three Considerations Before Getting Involved in Clinical Research

December 13, 2021 | Jill M Steiner, MD, FACC

Feature Article

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Many feel the pressure to do – and enjoy – research at every step of their medical training. Some feel that spark and run with it, and they go on to have successful research careers. But others are still trying to figure out how to be meaningfully involved in clinical research.

The traditional way to build a research career is to pursue mentored, grant-funded research in an academic setting. This often begins prior to or during fellowship and is comprised of a series of steps toward independence. A faculty appointment in a research or physician-scientist track means substantial time is protected for research, as stipulated by percent effort toward one or multiple grants. This time allocation may fluctuate depending on the project status, but on this track, promotion is often based on research and funding productivity. Because of its rigidity, the minority of cardiologists find themselves pursuing research in this manner.

More cardiologists become involved in research by other means, the simplest being to analyze existing medical records data. Conducting prospective and clinical trials research, however, requires much more time, infrastructure and effort. Time, or lack thereof, has been described as the main barrier to cardiologists' involvement in research. Still, it is never too late to do so, though t involvement may vary across practice models.

JACC Journals

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Journal of the American College of Cardiology

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Hypertensive Disorders of Pregnancy and Cardiovascular Risk: We Are Missing the Opportunity of a Lifetime*

ACCEL Lite: High-Sensitivity Troponin in The ED: Pearls And Pitfalls of Wide-spread Utilization

Jan 18, 2022 | Alison Bailey, MD, FACC; Ana Barac, MD, PhD, FACC; Fathima Aaysha Cader, MBBS, MD; Michael C. Kontos, MD, FACC

Podcast

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Use of the newer high-sensitivity troponins offer significant advantages, but with a number of caveats. Although the ability to accelerate the exclusion of myocardial infarction in many patients within just a few hours of ED presentation, the increased sensitivity can potentially lead to diagnostic confusion as more patients will have detectable troponin indicating myocardial injury not associated myocardial infarction.

In this interview, Michael C Kontos, MD, FACC, Ana Barac MD, PhD, FACC, with Aaysha Cader, MBBS, MD, MRCP, discuss High-Sensitivity Troponin in The ED: Pearls And Pitfalls of Wide-spread Utilization.

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Journal of the American College of Cardiology

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Global Burden of Cardiovascular Diseases and Risk Factors, 1990–2019: Update From the GBD 2019 Study

JACC State-Of-The-Art Review

Gregory A. Roth, George A. Mensah, Catherine O. Johnson, Giovanni Addol
Noël C. Barengo, Andrea Z. Beaton, Emelia J. Benjamin, Catherine P. Benzi

J Am Coll Cardiol. 2020 Dec, 76 (25) 2982–3021

JBC JOURNAL OF BIOLOGICAL CHEMISTRY OPEN ACCESS

RESEARCH ARTICLE | VOLUME 296, 100507, JANUARY 2021

Giant ankyrin-G regulates cardiac function

Omer Cavus • Jordan Williams • Hassan Musa • ... Thomas J. Hund • Peter J. Mohler • Elisa A. Bradley • Show all authors

Am J Hypertens. 2021 Sep 22;34(9):919-928. doi: 10.1093/ajh/hpab041.

Dietary Habits and Medications to Control Hypertension Among Women of Child-Bearing Age in the United States from 2001 to 2016

Lara C Kovell [1], Benjamin Maxner [2], Didem Ayturk [3], Tiffany A Moore Simas [3 4], Colleen M Harrington [1], David D McManus [1 3], Paula Gardiner [5], Gerard P Aurigemma [1], Stephen P Juraschek [6]

JACC Journals

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JACC: CardioOncology

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Decoding the Nanoenvironment in Cardiac Amyloidosis Through Proteomics*

Editorial Comment

Kevin M. Alexander, Alokkumar Jha, and Ronglih Liao

J Am Coll Cardiol CardioOnc. 2020 Nov, 2 (4) 644–646

Topic(s): Cardio-oncology, Basic & Translational Research, Amyloidosis

ACC Cardiology Hour With Dr. Valentin Fuster | ACC.22 Day 3

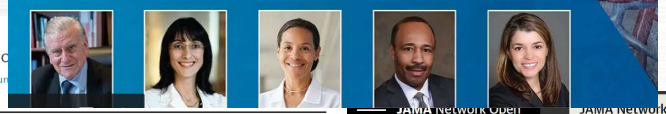
From a medical journal

EXPERT ANALYSIS ON TOP TRIALS FROM ACC.22

ACC CARDIOLOGY HOUR

AMERICAN COLLEGE of CARDIOLOGY

An Expert Video Panel Led by Valentin Fuster, MD, PhD, MACC



THROMBOSIS RESEARCH

Submit Log in

REVIEW ARTICLE | VOLUME 136, ISSUE 3, P493-503, SEPTEMBER 01, 2015

Understanding the role of prostaglandin E_2 in regulating human platelet activity in health and disease

Eitan A. Friedman • Martin L. Ogletree • Elias V. Haddad • Olivier Boutaud

ELSEVIER

Review Article

Sarcoidosis-Related Cardiomyopathy: Current Knowledge, Challenges, and Future Perspectives State-of-the-Art Review

NISHA A. Gilotra MD [1], JAN M. GRIFFIN MD [2], NOELLE PAVLOVIC MSN, RN [3], BRIAN A. HOUSTON MD [4], JESSICA CHASLER PharmD, MPH [5], COLLEEN GOETZ CRNP [6], JONATHAN CHRISPIN MD [7], MICHELLE SHARP MD, MHS [8], EDWARD K. KASPER MD [1], EDWARD S. CHEN MD [8], RON BLANKSTEIN MD [9], LESLIE T. COOPER MD [10], EMER JOYCE MBBCh, PhD [11], FAROOQ H. SHEIKH MD [6]

JAMA Network Open | JAMA Network Open | Enter Search Term

Invited Commentary | Nephrology

June 7, 2022

More

Sex Differences in Blood Pressure—A Measured Relook at Measures

Natalie A. Bello, MD, MPH[1]; Susan Cheng, MD, MPH[1]

CTR Upping Your Game Alumni Perspective: LaPrincess Brewer, MD, MPH

- Cardiologist and Physician-scientist; Mayo Clinic Department of Cardiovascular Medicine, Rochester, MN
- **Clinical focus:** Prevention, Cardiac Rehabilitation
- **Research Focus:**
  - Community-based participatory research approaches
  - Digital health interventions in diverse populations
  - Social determinants of health
- **How CRT helped me:**
  - Provided critical skills in grant infrastructure/ development
  - Awarded Winn Career Development Award, 2022-2024 supports community-oriented clinical trial

ROBERT A. WINN DIVERSITY IN CLINICAL TRIALS AWARD PROGRAM
Established by the Bristol Myers Squibb Foundation

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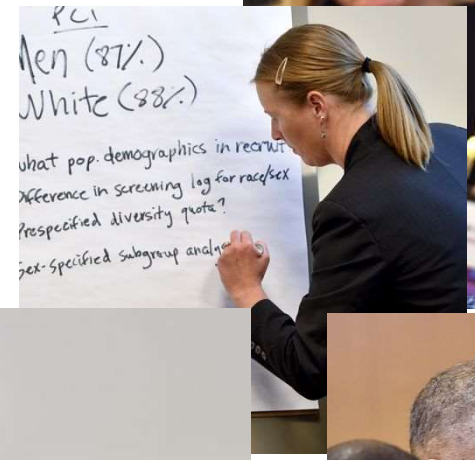
Men (87%)
White (88%)
what pop. demographics in recruit
difference in screening log for race/sex
prespecified diversity quota?


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Clinical Trials Research Program

Please welcome CTR learners:

- Saurav Chatterjee, MD, FACC
- Samuel Kim, MD, FACC
- Anu Lala, MD, FACC

CTR Learner Directory

- Available as PDF in IAF materials
- Email Diversity@acc.org to receive hard copy via mail

We are grateful to our supporters for their commitment to ACC's Clinical Trials Research: Upping Your Game Program.

2020-2022 Cohorts

Bristol Myers Squibb™

2019 Cohort

AMGEN

Bristol Myers Squibb™

and contributors to ACC's Campaign for the Future

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Advancing Heart Care Worldwide

The Impact of a Diverse Investigator Workforce on the Future

Panel Discussion – Moderated by Mary Norine Walsh, MD, MACC

- **Melvin Echols, MD, FACC –** Morehouse experience
- **Brendan Mullen** – ACC efforts to diversify with data tools
- **Robert Roswell, MD, FACC** – Northwell Health
- **Leticia Ferri, MD** – Bristol Myers Squibb perspective
- **Christin Coffeen, MS, LCGC** – Illumina perspective

Melvin Echols, MD, FACC

Morehouse School of Medicine

ACC Chief Diversity, Equity & Inclusion Officer

INDUSTRY ADVISORY FORUM

AMERICAN COLLEGE of CARDIOLOGY®

Quantifying Diversity to Use Diversity

Brendan Mullen, EVP, American College of Cardiology

Although this may seem a paradox, all exact science is dominated by the idea of approximation. Every observer admits that he is likely wrong and knows about how much wrong he is likely to be.

-Bertrand Russel, 1931

A system for mathematically defining social diversity based on population characteristics

Individual Rarity Ratio: A measure of rarity of the class of the selected individual in comparison to the most common class in the population; *i.e. the individual is x times rarer than the most common individual*

$$IRR = f^{-1}\left(P_i^{C_i}/P_i^{C_m} \middle| i^{C_i} \in N, \sum i^{C_i} = N\right) = \frac{P\left(x_i^{C_m}\right)_N}{P\left(x_i^{C_i}\right)_N}$$

Group Diversity Index: A modified ratio of the composition of the sample group to the composition of the population; a sample dominated by the majority class produces an GDI of 0 or near 0; a perfectly representative sample produces a GDI of 1; and a highly diverse sample produces a score ≥ 1

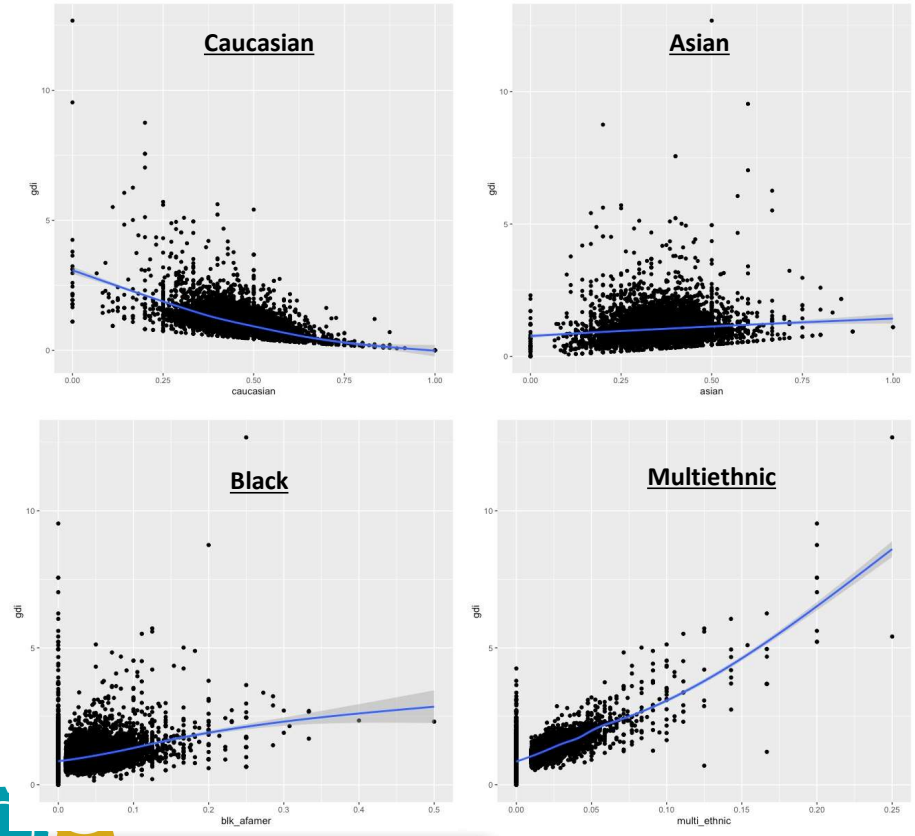
$$SDI = \frac{\sum_i^{C_i}\left(\frac{x_i^{C_i} x_i^{\emptyset m}}{S^2\left(P\left(X_i^{C_i}\right)_N P\left(X_i^{\emptyset m}\right)_N\right)}\right)}{\sum C_i}$$

Class Coverage Score: The percentage of all classes in the population represented in the sample.

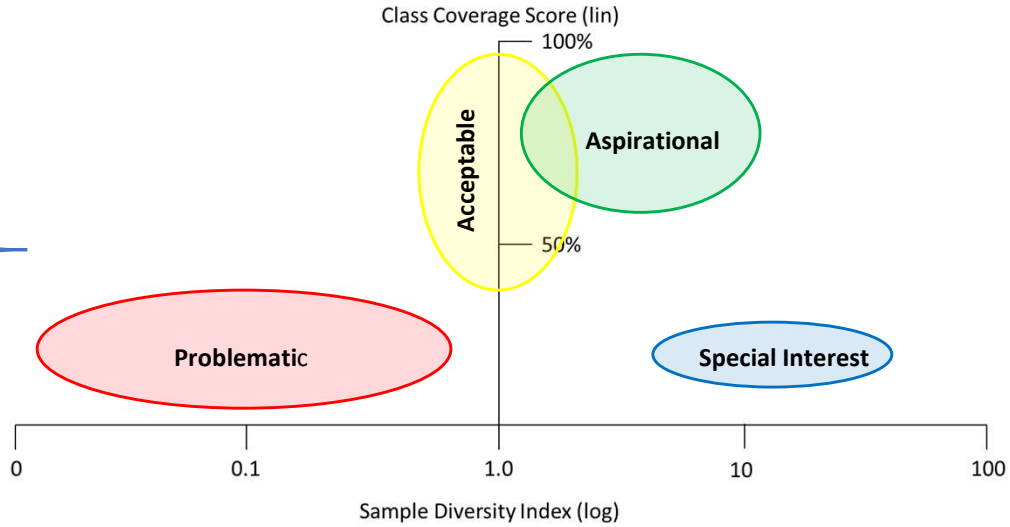
$$CCS = \frac{\sum C_{S,G}}{\sum C_N}$$

Testing and applying the GDI

Modeling Group Diversity Index characteristics



Normative assessments of quantitative diversity scoring



- Ability to assess current state of committee diversity
- Set goals and track progress
- Identify best practices and positive deviants

Solving the ‘Friends and Family Problem’

This haystack is full of needles!!!

PubMed

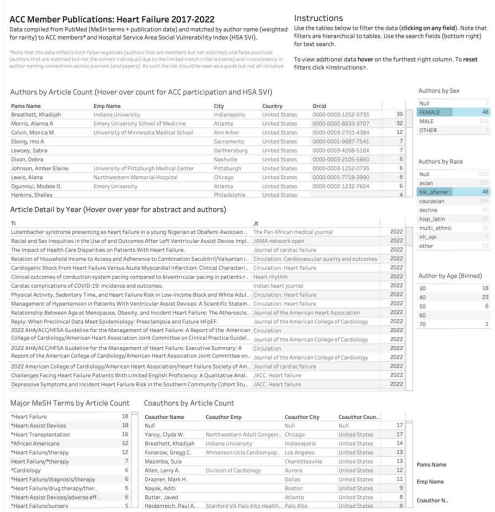
+

AMERICAN COLLEGE of CARDIOLOGY

Member Database

Integrated database of academic publication, clinical credentials, and demographics

Member Finder



- Search any clinical domain using MeSH
- Sort by age, sex, race/ethnicity, geography, tenure, prolificacy, H-index, etc.
- Assess expertise, research focus, coauthors and collaborator networks
- Assess participation in ACC activities and committees
- Social depravation index of practice geography

Rethinking trial site selection to meet the diversity imperative

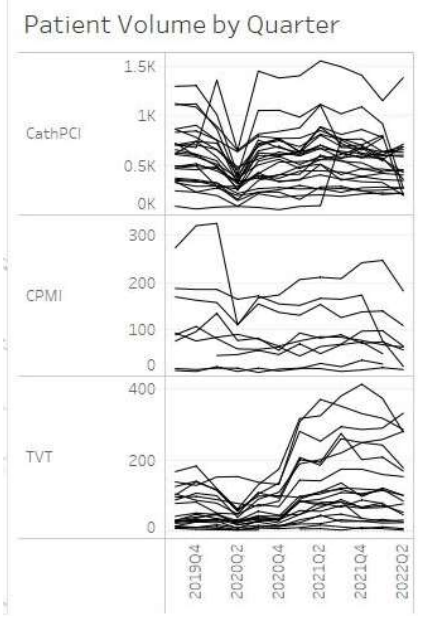
NCDR knows the centers with the greatest patient diversity…

…the demographic composition of Mesh those populations …

Patient Volume by Race

American Indian/Alaskan Native	406
Asian	23,944
Asian-Indian	6,037
Black/African American	31,596
Chinese	3,441
Filipino	2,573
Guamanian or Chamorro	23
Japanese	616
Korean	4,107
Native Hawaiian	379
Native Hawaiian/Pacific Islander	1,087
Other Asian	5,962
Other Pacific Islander	434
Samoan	111
Vietnamese	5,408
White	109,049

…and how patient populations change over time by site and procedure!



INDUSTRY ADVISORY FORUM
AMERICAN COLLEGE of CARDIOLOGY®

Well, I'll be damned, this haystack is also full of needles!

Robert Roswell, MD, FACC

Northwell Health

Leticia Ferri, MD

Bristol Myers Squibb

Diversifying the Trial Workforce

Christin Coffeen, MS, LCGC
Senior Manager, Medical Affairs, Illumina
ccoffeen@illumina.com
+1.650.474.9021

Disclosures and Disclaimers

I am an employee of and hold equity in Illumina.

OUR MISSION

Unlocking the power of the genome to improve human health

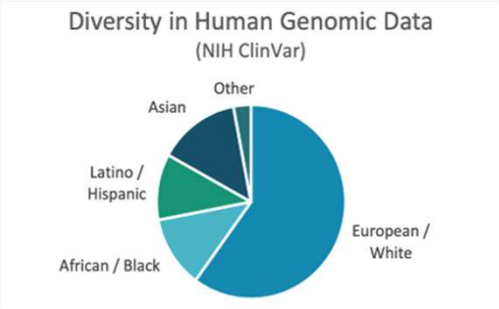
Precision Medicine

*"Precision medicine is an innovative approach that uses information about an individual's **genomic, environmental and lifestyle information** to guide decisions related to their **medical management**. The goal of precision medicine is to provide more a **precise approach** for the prevention, diagnosis and treatment of disease". - National Human Genome Research Institute*

- The success of the evolving field of precision medicine has been driven by the evolution of science and technology, which has enabled the sequencing of the human genetic code; the development of bioinformatic tools to process the vast amounts of genomic data generated; and the creation of databases that curate, organize, and share the information[1].
- Genomic databases are important and serve as a repository for shared knowledge related to the numerous research studies and clinical case reports that contribute to knowledge of the impact of genetics on human health, as well as a basic understanding of genetic differences between human beings[1].

1.Landry et al, Health Affairs,2018; 37:780

What is diversity?



Data Diversity*

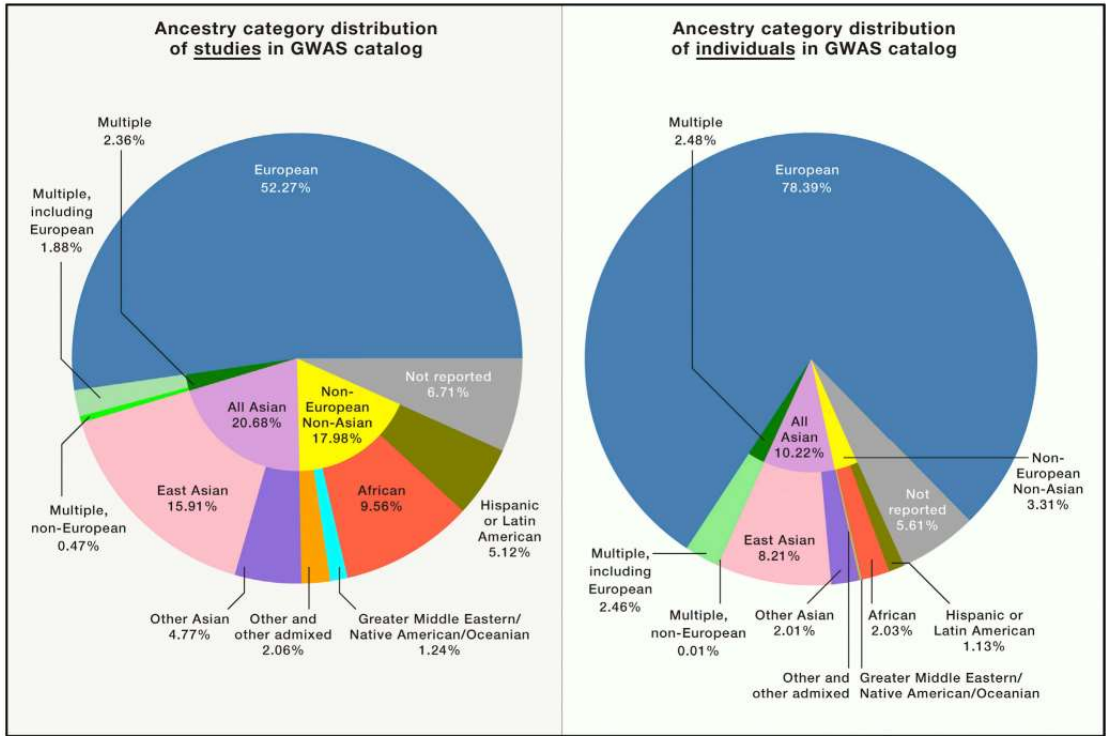
Workforce Diversity

Equitable Access

*Popejoy AB et al, Hum Mutat, 2018, 39(11): 1713-1720.

Data Diversity

GWAS Studies by Ancestry in the GWAS Catalog[1] (2019)

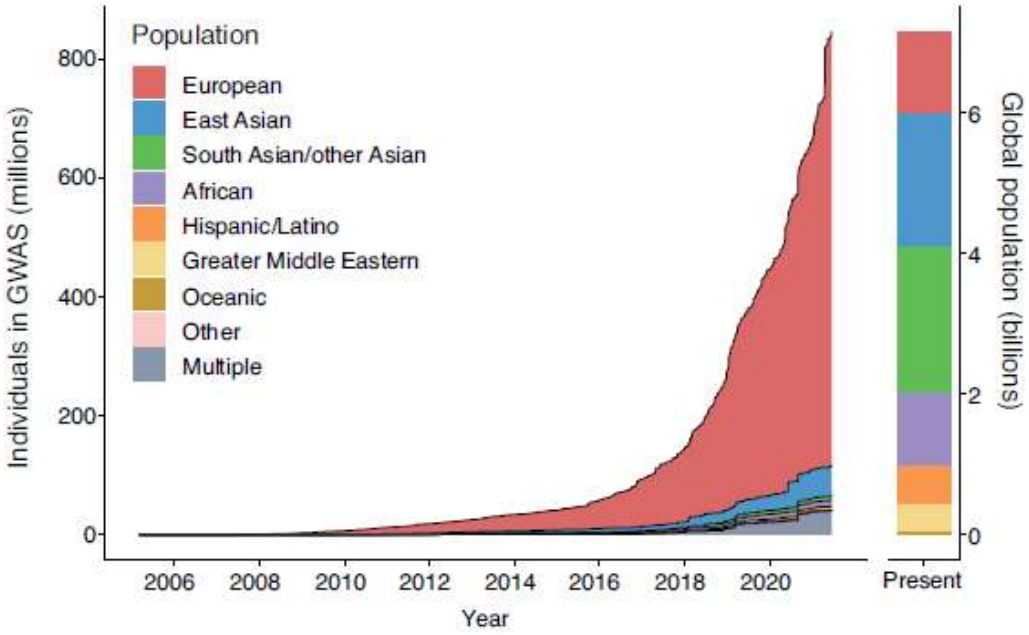


- Data from people of European ancestry accounts for at least 78% of GWAS while Individuals of African ancestry account for 2.4%[2]
- Over 70% GWAS come from only three countries - USA, Iceland and UK[2]
- While people of African ancestry (comprising of black African, black Caribbean and black 'other') constitute 3.4% of the UK population (according to the 2011 census), their representation in UK Biobank constitutes only 1.6%[2]
- Conversely, white British participants constitute 94% while making up 91.3% of the population[2]

1. Sirugo et al. Cell, 2019; 177:26-31
2.Atutornu et al, eBioMedicine 2022;76:103879

Data Diversity

*The proportion of samples from individuals cumulatively reported by the GWAS Catalog as of 8 July 2021**

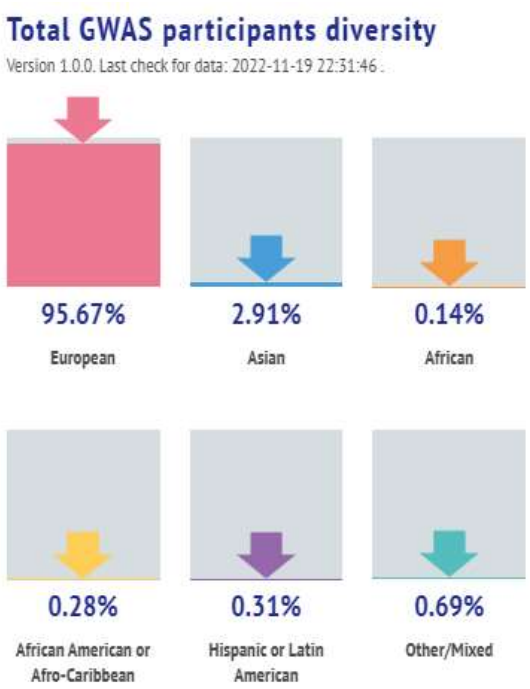


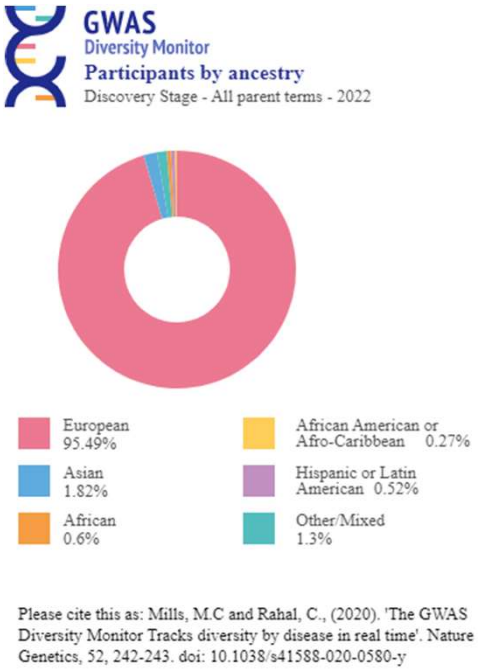
- As June 2021, the vast majority (86%) of genomics studies have been conducted in individuals of European descent, which represents an increase from 81% in 2016
- At the same time, the proportion of studies conducted in underrepresented populations have either stagnated or decreased
- Genetic studies including participants with multiple ancestries have increased but only very slightly, to 4.8%
- This shows that progress toward diversification has been painfully slow

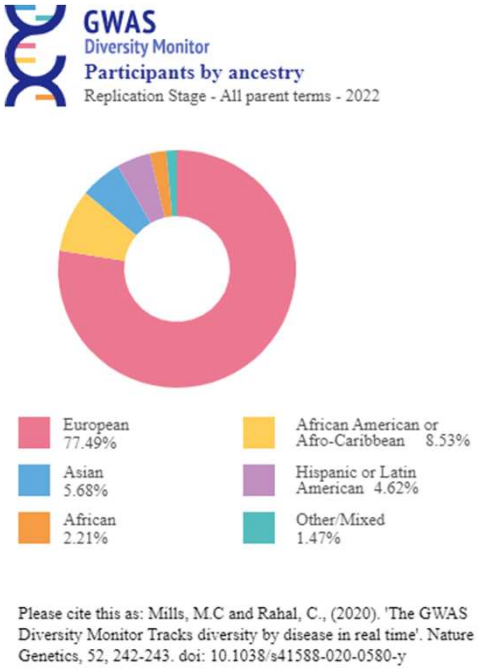
*Futamo S et al, Nature Medicine, 2022; 28: 243–250

Data Diversity

GWAS Participant Diversity 2022







Discovery Stage

Replication Stage

The GWAS Diversity Monitor; https://gwasdiversitymonitor.com/ Access on 20 Nov 2022

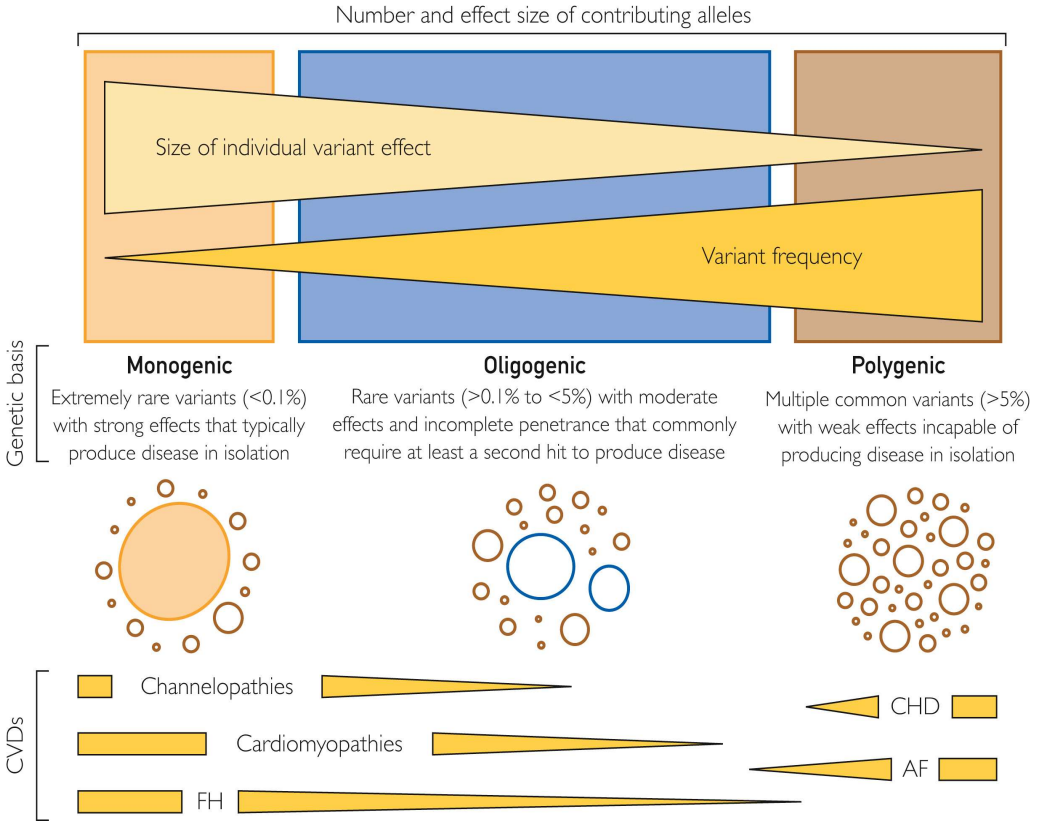
Lack of Diversity in Discovery Studies Has Consequences

Monogenic vs. Polygenic

Monogenic
- Long QT syndrome
- Hypertrophic cardiomyopathy (HCM)
- Familial hypercholesterolemia (FH)

Oligogenic
- Arrhythmogenic cardiomyopathy (ARVC)

Polygenic
- Coronary artery disease (CAD)
- Atrial fibrillation (AF)

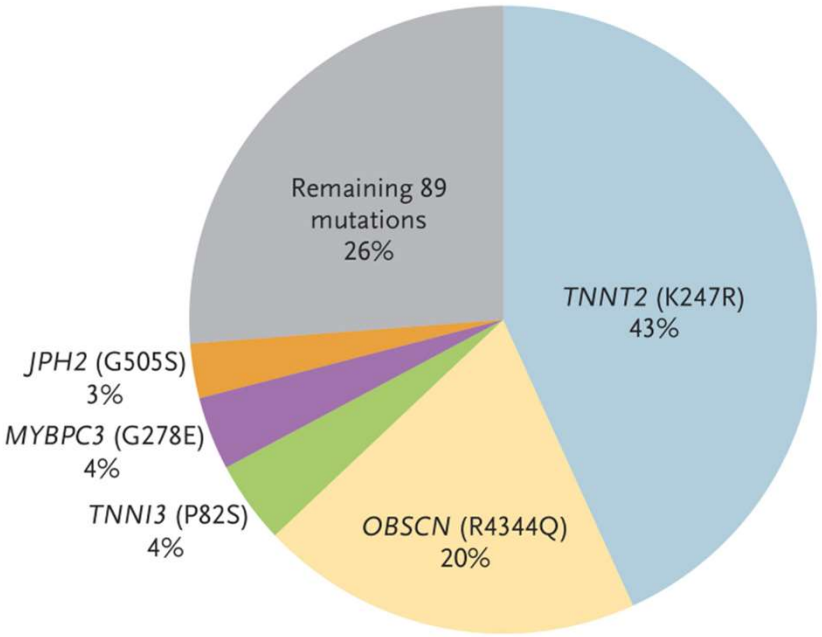


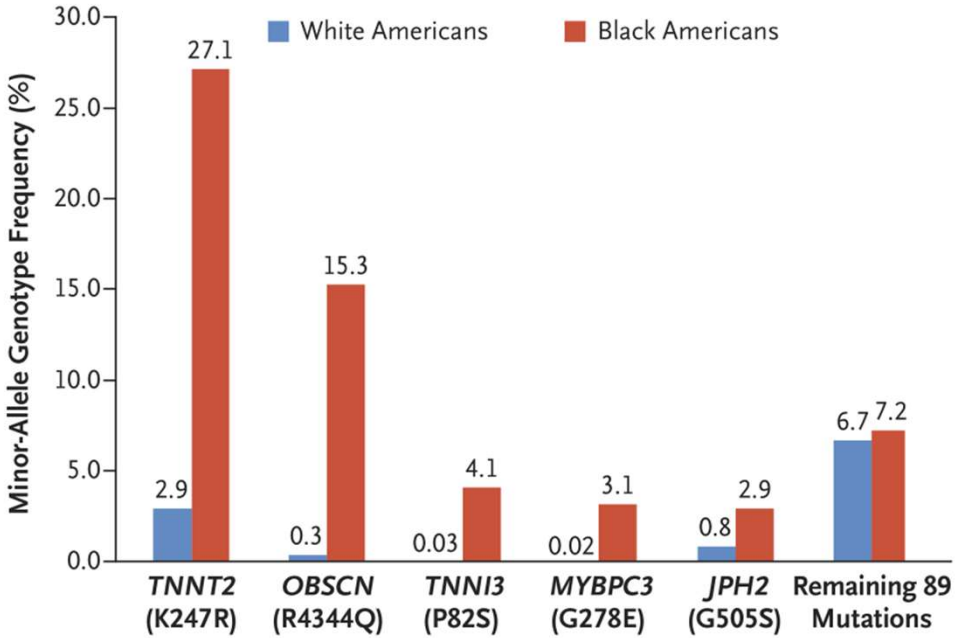
Giudicessi, JR, *et al.* Precision Cardiovascular Medicine: State of Genetic Testing. Mayo Clinic Proceedings 2017 92642-662DOI: (10.1016/j.mayocp.2017.01.015)

Lack of Diversity in Discovery Studies Has Consequences

Misclassified pathogenic variants lead to false positive reports

Genetic Variants Associated with Hypertrophic Cardiomyopathy



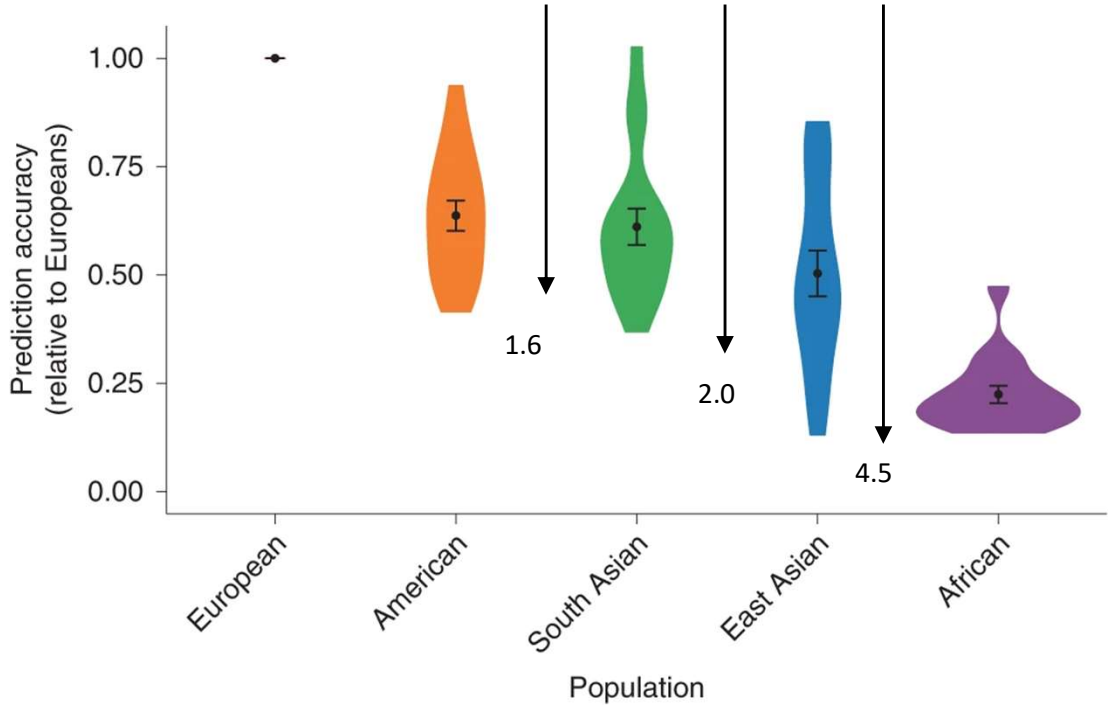


Manrai AK et al. N Engl J Med 2016;375:655-665.

Lack of Diversity in Discovery Studies Has Consequences

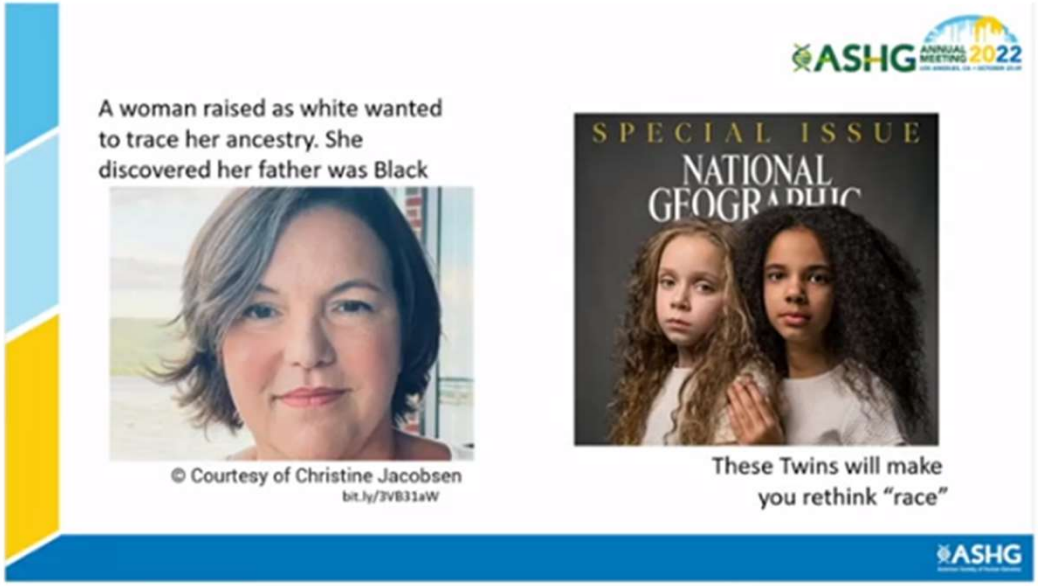
Current Polygenic Risk Scores May Exacerbate Health Disparities

"the accuracy of genetic-risk prediction will decay with increasing genetic divergence between the original GWAS sample and the target of prediction, a function of population history.."-Martin et.al.



Martin, A.R., Kanai, M., Kamatani, Y. *et al.* Clinical use of current polygenic risk scores may exacerbate health disparities. *Nat Genet* **51,** 584–591 (2019). https://doi.org/10.1038/s41588-019-0379-x

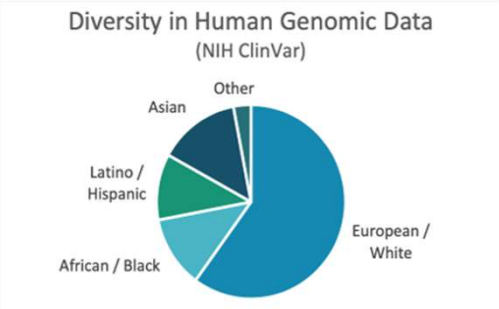
ASHG 2022 Presidential Address – One Human Race: Billions of Genomes



Speaker: ASHG President, Charles Rotimi, PhD

https://www.ashg.org/meetings/2022-annual-meeting/presidential-address/

What is Illumina doing?



Data Diversity*

Workforce Diversity

Equitable Access

*Popejoy AB et al, Hum Mutat, 2018, 39(11): 1713-1720.

ASHG Genetics & Genomics Impact Partners

American Society of Human Genetics

Dedicated to advancing human genetics and genomics through ongoing dialogue and philanthropic engagements, knowing that collective effort is required to ensure all people benefit from genetics and genomics research.

1	Acknowledging and addressing inequities in human genetics and genomics
2	Expanding participation and strengthening careers of researchers from diverse backgrounds
3	Sustaining emphasis on increasing diversity and inclusion in research cohorts
4	Developing a knowledge network and professional education for researchers

https://www.ashg.org/about/partnerships/#:~:text=ASHG%20Genetics%20and%20Genomics%20Impact,human%20genetics%20and%20genomics%20research.

iHope Global Network

Providing clinical whole-genome sequencing to patients in need

illumina

GENOME ONE

HUDSONALPHA INSTITUTE FOR BIOTECHNOLOGY

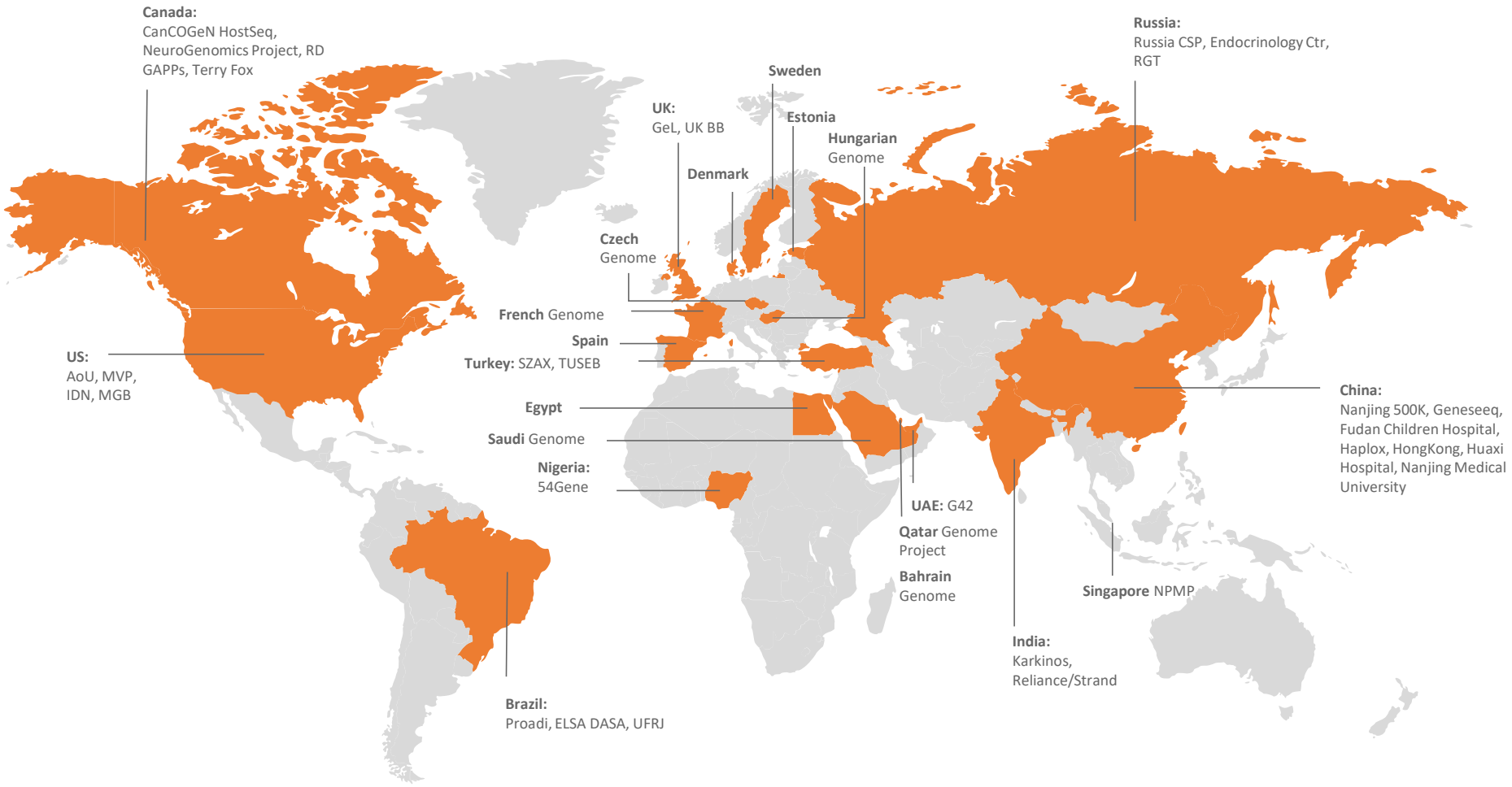
GeneDx

NEW YORK GENOME CENTER

https://www.illumina.com/company/ihope.html

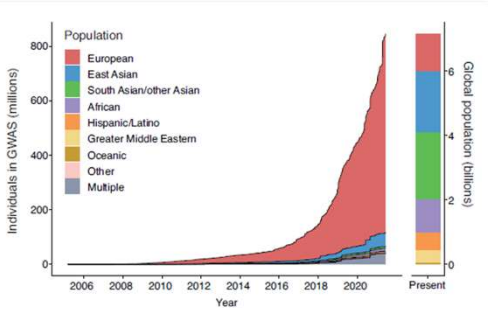
Ongoing Efforts

- All of Us–U.S. based project started in 2018. Aims to sequence 1 million diverse genomes over the next decade.
- GenomeAsia 100K—Started in Singapore in 2016, this project aims to sequence 100,000 genomes from across Asia.
- BioBank Japan—Began in 2003, the project recruited 260,000 patients representing 440,000 cases of 51 primarily multifactorial (common) diseases.
- The Qatar Genome Programme—This pilot phase of this project started in 2015 and aims to sequence the genomes of 350,000 inhabitants of Qatar.
- Genome India Project—Started in 2020, this project aims to sequence 10,000 genomes across the country.
- Human Heredity and Health in Africa (H3Africa)—A consortium begun in 2011 that links up researchers in human genetics around the country and facilitates genomic studies.



Illumina: Internal data

What is diversity?



Data Diversity*

Workforce Diversity

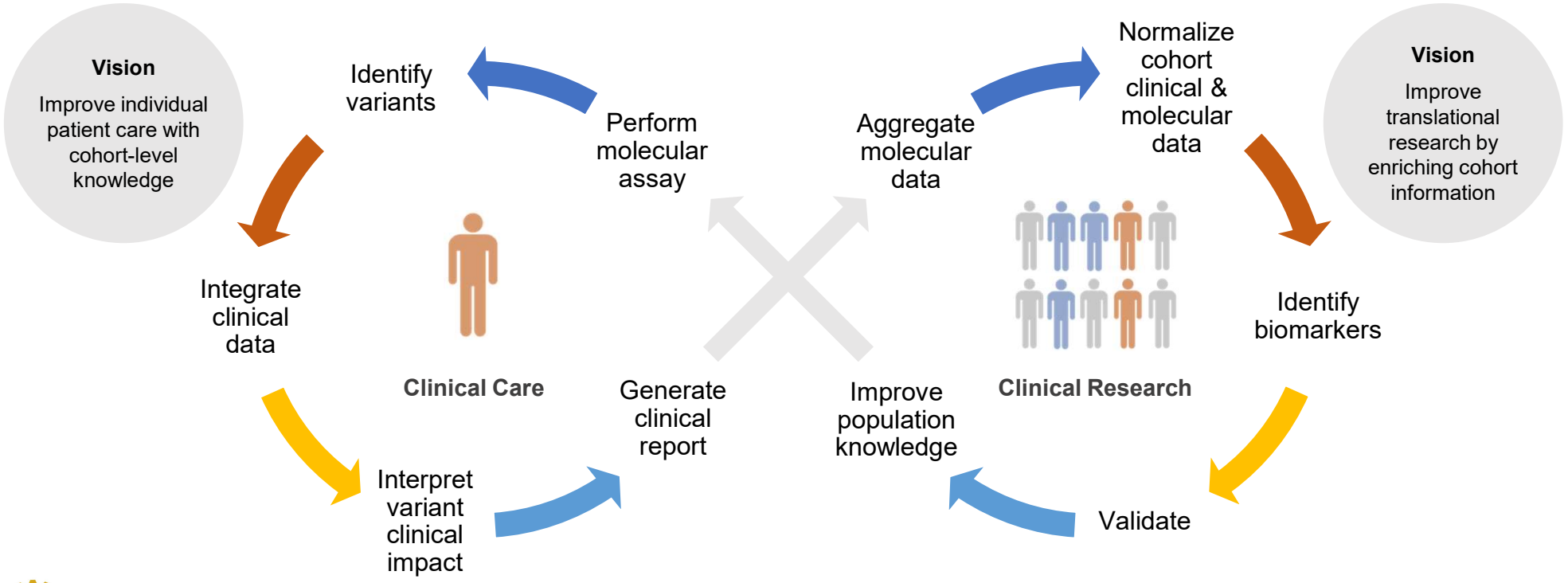
Equitable Access

*Futamo S et al, Nature Medicine, 2022; 28: 243–250

As an Example…..

Concept of a Learning Health System

The Infinite Cycle of Genomic Medicine



Fully Reap the Benefits of Big Data in the Context of Clinical Care

Conclusions

- Despite some notable efforts, representation of non-European ancestry groups in genetic research remains low, and this affects diverse global populations.
- The benefits of greater diversity extend beyond the studied population. Focus on building respectful and collaborative partnerships with diverse and under-represented populations who will participate in studies is crucial.
- To be successful in achieving equitable inclusion of underrepresented groups in genomic studies, the stakeholders must stimulate local participation, build trust and ensure mutual respect.

1. Futamo S et al, Nature Medicine, 2022; 28: 243–250

“The commitment we’re sharing will help the researchers of today and tomorrow to make new discoveries that serve populations worldwide, apply genetics knowledge in more just and equitable ways, and inspire and support others to join the field.”

Charles Rotimi, PhD
ASHG President

Thank you!

Christin Coffeen, MS, LCGC

Senior Manager, Medical Affairs, Illumina

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Appendix

The African Genome is underrepresented in global heath data sets

80%

Of available genomic data only represents 16% of the global population (those with European ancestory)*

Africa

Is the continent with the highest amount of genetic diversity, it is underrepresented in global genomic databases.
Genomics and other omics in African populations can overcome some of the challenges and open new opportunities to further insight in human biology and broadening diversity could in the future improve clinical care for everyone.

Goal

Raise awareness through a program targeting genetic discovery Principle Investigators (PIs) in non-European populations (in this instance, targeting Africa).

Primary Need: GWAS data generation

Work with you to find out how we can better collaborate in future.

* Martin, A.R., Kanai, M., Kamatani, Y. et al. Clinical use of current polygenic risk scores may exacerbate health disparities. Nat Genet 51, 584–591 (2019). https://doi.org/10.1038/s41588-019-0379-x

Eurocentric biases in genetics studies are not only inequitable, but also result in major missed scientific opportunities.

- Such as –
  - Identification of new associations with population-enriched variants
  - Pinpointing causal variants for functional follow-up
  - Improving genetic risk prediction accuracy for all populations understanding shared versus unique genetic and environmental population risk factors that influence health outcomes[1,2,3]
- This bias effectively translates into poorer disease prediction and treatment for individuals of under-represented ancestries[4]
- Importantly, studying diverse populations increases our ability to broadly understand genetic disease architectures that will, ultimately, lead to increased precision in medical care[4]

1. Inouye, M. et al. *J. Am. Coll. Cardiol. 2018;* **72**:1883–1893 . 2, Fatumo, S. *EBioMedicine, 2020;* **54**:102721 3. Fatumo, S. et al. *Hum. Mol. Genet.2021;* **30**:1559–1568. 4. Sirugo et al. Cell, 2019; 177:26-31

Factors Contributing to Current Inequalities[1]

- Socio-economic disadvantages, access to care, and geographical proximity to institutions of academic medicine; lack resources such as funds, institutional capacity and a skilled workforce are major barriers to genomic research
- The dominance of European and American scientists in genomic research stems from advances in genomic technologies, infrastructure, and the better funding opportunities; the lack of diversity among researchers is a crucial driver of bias in genetic studies
- The burden of historical injustices including coercion and deception in research and negative experience with the healthcare system results in lack of trust in research
- Mutual suspicion and lack of trust is a significant cause for scientists to avoid enrolling indigenous groups and for indigenous groups to avoid participating in research.
- For low- and middle-income countries Lack of expertise in ethical, legal and social implications relevant to genomics research has hindered the conduct of research and data sharing

1. Mapes et al, Clin Cancer Res 2018;

Step to Improve the Participation of Underrepresented Groups

- Lack of engagement of traditionally scientifically underrepresented groups with genomics could be addressed by culturally and linguistically appropriate engagement practices
- Acknowledgement that a fair and just genomic medicine service can only be delivered if the data that guides genomic variant interpretation is populated by DNA from ancestrally diverse people.
- Need to engage public groups globally, to understand their concerns and hesitations related to genomic data collection, and to act in relation to these concerns to build genomic research and medicine initiatives that are worthy of public trust

Atutornu et al, eBioMedicine 2022;76: 103879

Step to Improve the Participation of Underrepresented Groups

Stakeholder Will

- Boldness and willingness of the varied stakeholders, including research institutions, researchers, participants, funders and governments, to collaboratively work together to address this imbalance
- Research institutions must be willing to ensure they have a diverse workforce.

Funding

- Willingness to set up strategic schemes that promote research of underrepresented population groups
- Genomic research in underrepresented population groups require more time and resources and funders need to be able to commit to this
- Collaborations between local investigators and those from research-intensive nations are critical for funding success.
- Collaborations can provide diverse expertise including experience in grant writing, administrative support and the necessary local expertise and knowledge about the target population

1.Futamo S et al, Nature Medicine, 2022; 28: 243–250

Step to Improve the Participation of Underrepresented Groups

Infrastructure and administrative components

- Access to infrastructure for steps such as sample collection, processing, biobanking, genotyping or sequencing and computational analysis
- A comprehensive understanding of ethical concerns, regulations and policies to avoid major delays in cross-border shipping of biological samples, ability to reuse/share these valuable datasets in future
- Implementation of necessary material and data transfer agreements to ensure efficient movement of sample sand data.

Capacity building & Partnership with global consortia

- Education models to train and retain individuals locally to create a critical mass
- Increasing diversity in genomic studies contributes to more robust findings from replicated results as well as new discoveries, particularly when combined with existing large-scale studies
- Developing local research capacity enables contributions to global genomics consortia

Futamo S et al, Nature Medicine, 2022; 28: 243–250

Workforce Diversity – Trial Investigators

- How can ACC and industry work together to build a pipeline of diverse researchers? Is there more that ACC should be doing to encourage diverse researchers?
- What does industry want to see in emerging researchers? What competencies and experience are necessary for success?
- What opportunities could industry offer emerging researchers? Are there specific entry points where researchers could best be exposed to and/or benefit from industry efforts?

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#TRANSFORMCVCARE

Why Clinical Trial Diversity Matters

December 8, 2022

Industry Advisory Forum

Melvin R. Echols, MD, FACC, FHFSA, FASPC
Associate Professor of Medicine
Associate Director, Cardiovascular Research Institute
Morehouse School of Medicine
Chief Diversity, Equity, and Inclusion Officer
American College of Cardiology

Disclosures

- Abbott – Consulting
- Novartis – PARAGLIDE-HF, V-INCEPTION
- NovoNordisk – National Leader for HERMES Trial
- Occlutech – FROST-HF Executive Selection Committee
- NHLBI – REACT-AF DMSB
- HFSA – REIMAGINE-HF Steering Committee Co-Chair

Ongoing Studies

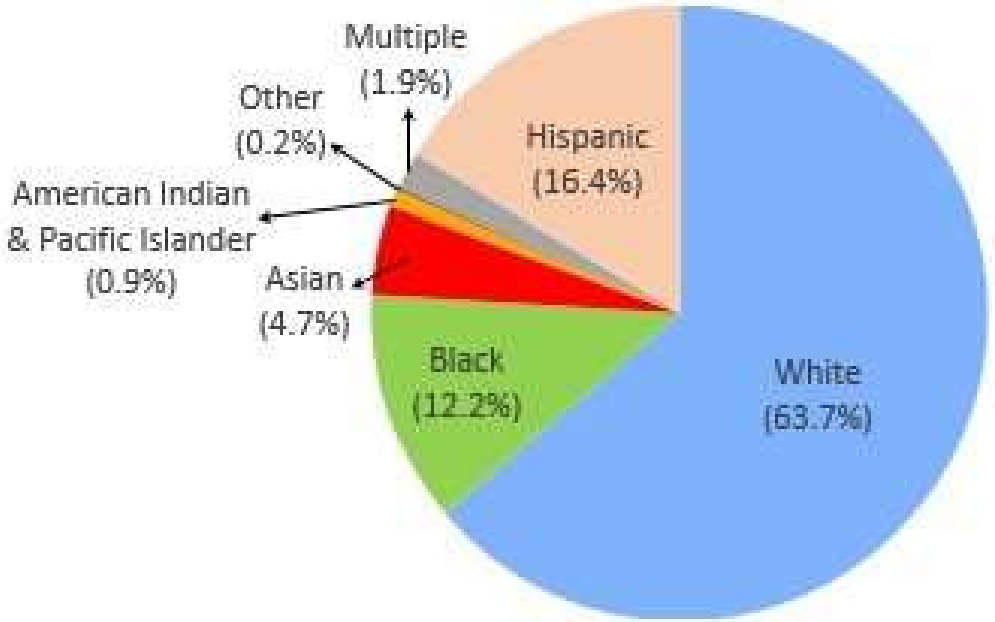
- Utilization of Population Based HF Scoring for Hypertensive HF – GA CTSA – PI
- PARAGLIDE-HF (Novartis) – Site PI
- ACTIVE-4 (NIH) – Site PI
- Long-Haulers Digi-clinical phenotyping (Truist) – Co PI
- SUMMIT (Lilly) – Site PI
- Transcriptome-HF (Tx Award)- PI
- V-INCEPTION (Novartis) – Site PI
- OCEANIC-AF (Bayer) – Site PI
- PEARL-AF (Duke) – Steering Committee
- HERMES (NovoNordisk) – US National Leader
- RE-IMAGINE HF (HFSA) – Co-Chair Steering Committee
- FROST – HF (Occultech) – Executive Selection Committee
- REACT-AF – Data Monitoring and Safety Board
- TIDE/HTN 2T (AHA SFRN)- Co PI

OBJECTIVES

- Why does clinical trial diversity matter

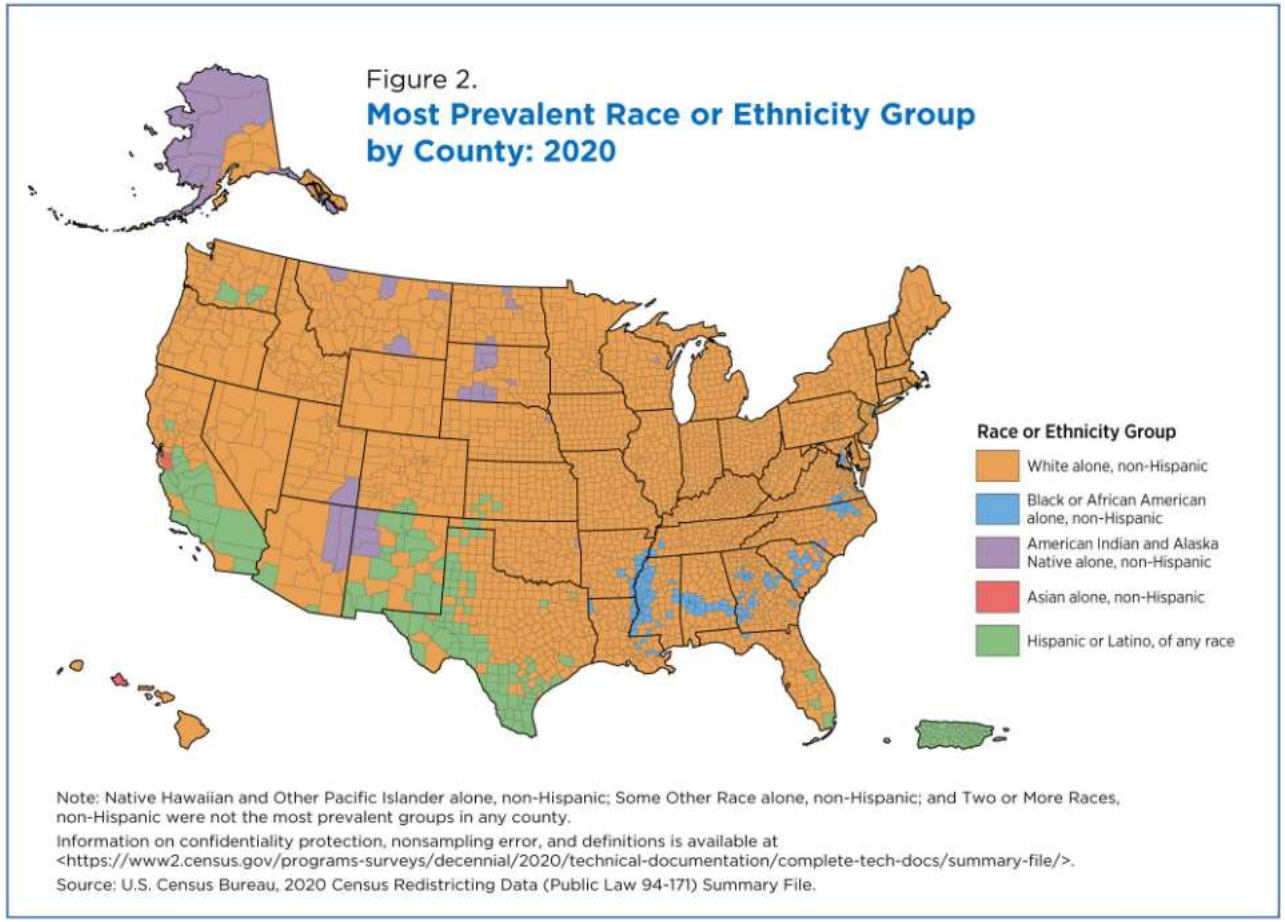
- Summarize the most contemporary and effective strategies to improve clinical trial recruitment equity

US Race and Ethnicity combined



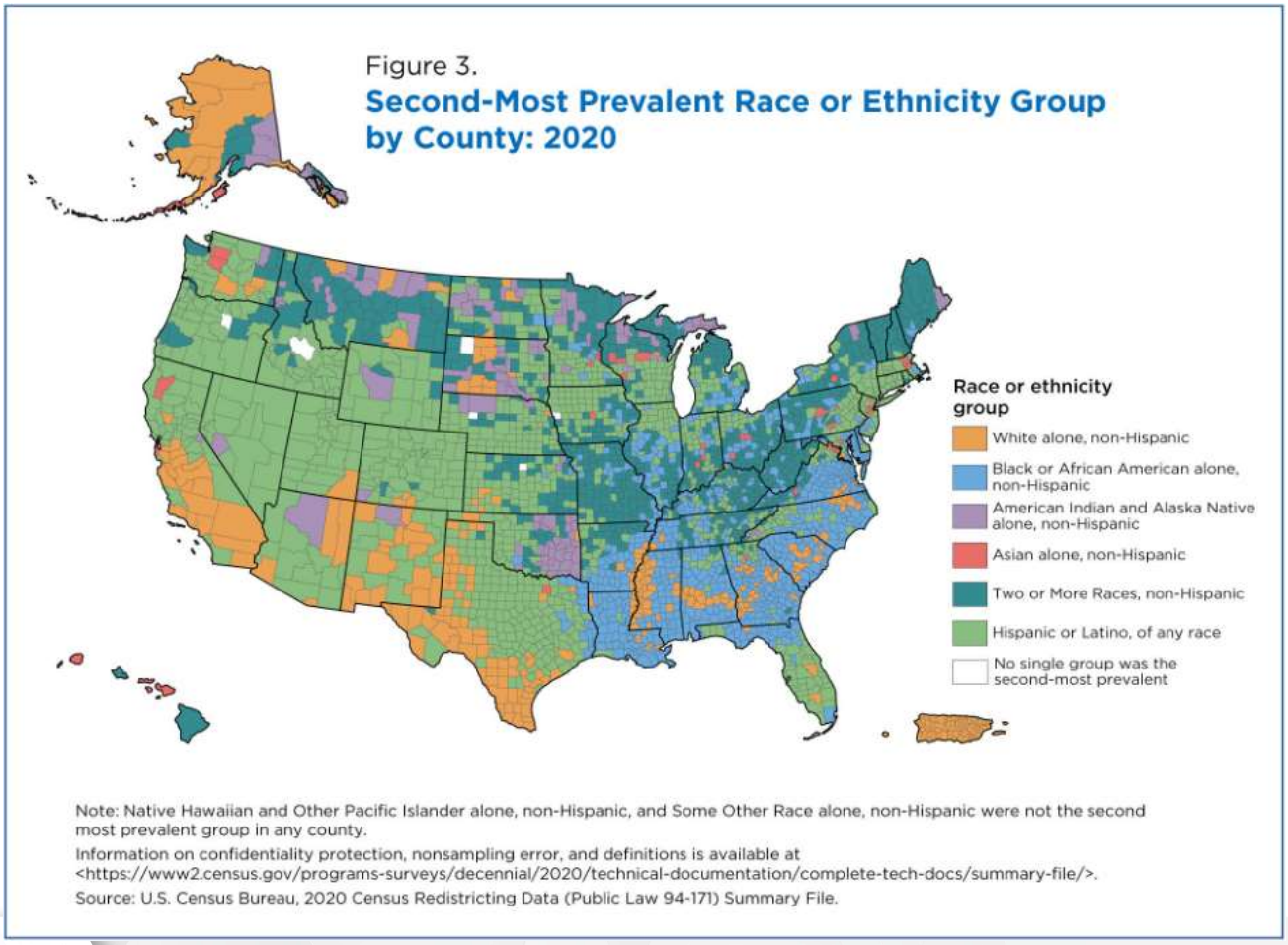
Data Source: 2010 US Decennial Census

RACE/ETHNICITY UNITED STATES



https://www.census.gov/library/stories/2021/08/2020-united-states-population-more-racially-ethnically-diverse-than-2010.html

RACE/ETHNICITY UNITED STATES



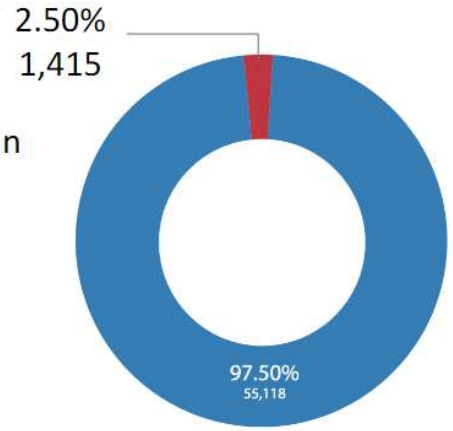
https://www.census.gov/library/stories/2021/08/2020-united-states-population-more-racially-ethnically-diverse-than-2010.html

Participation of Black or African American individuals in clinical trials for oncology, cardiology, and psychiatry

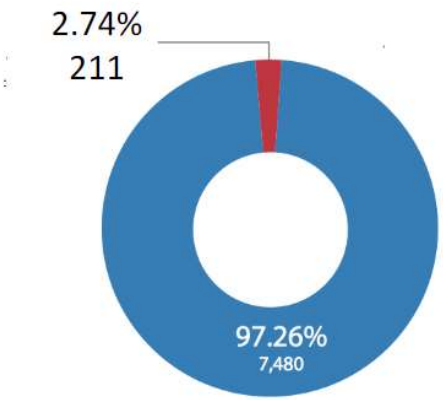
Black/African

Other race

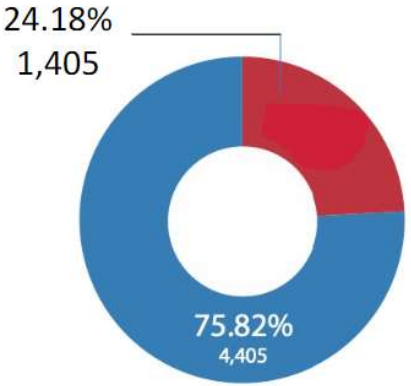
2015-2016



Cardiovascular Disease
N = 92,329

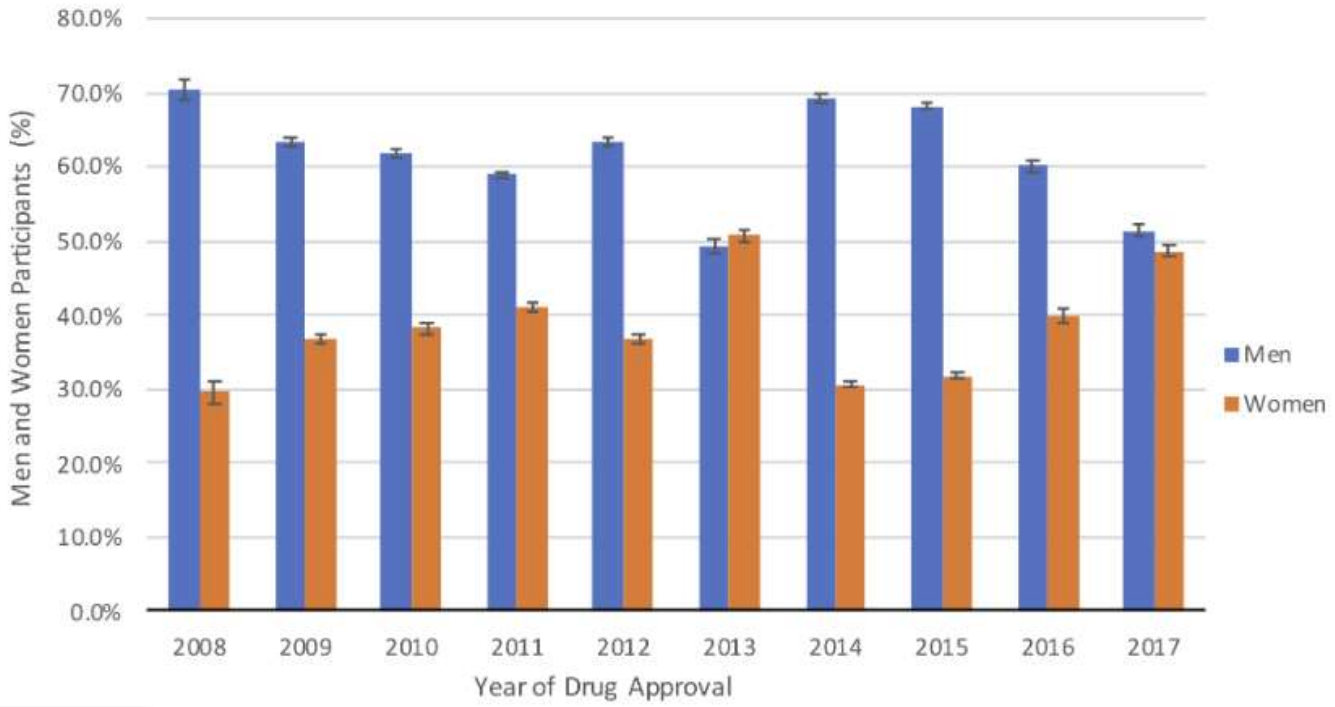


Oncology
N = 7,691



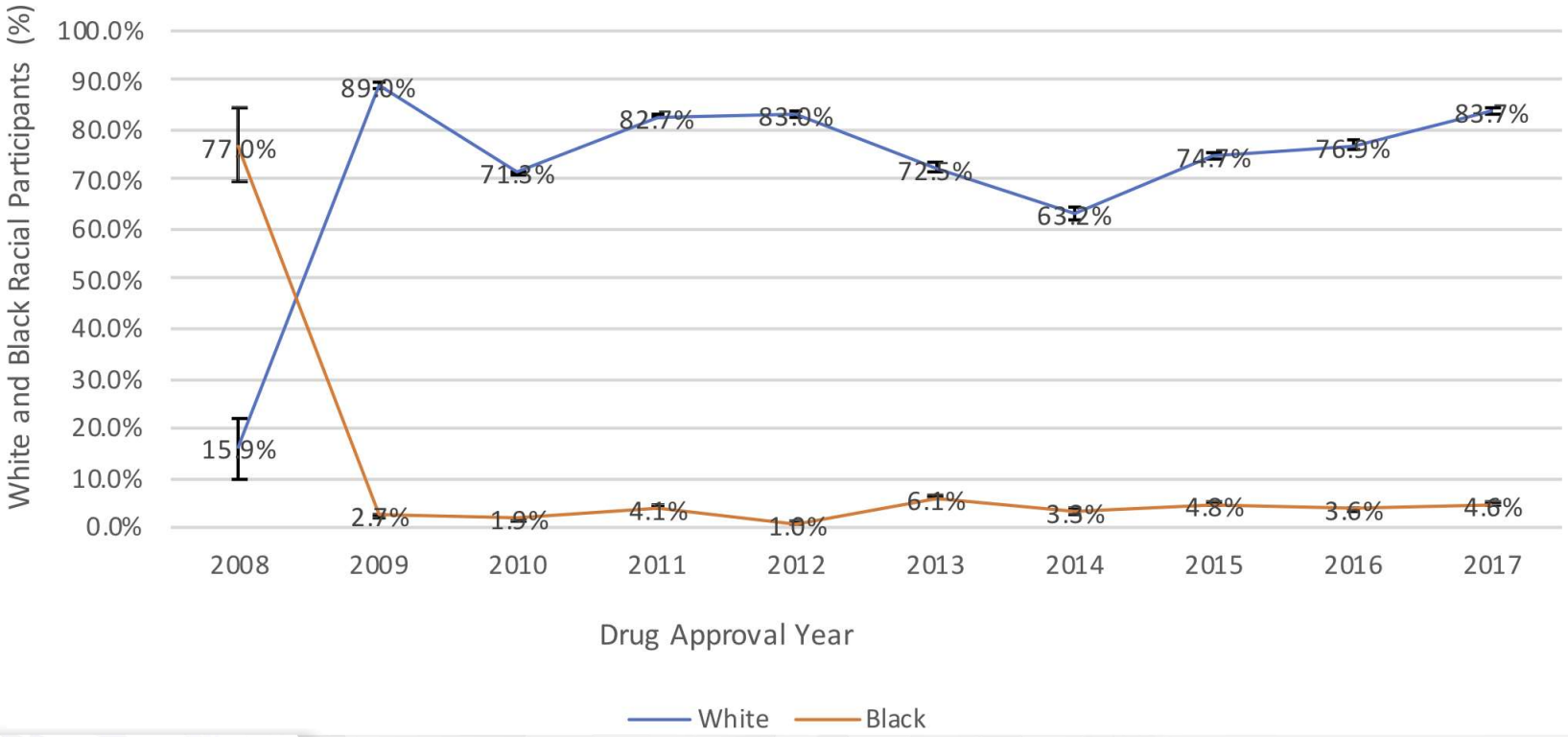
Psychiatry
N = 5,810

Percentage of men and women participating overall in cardiovascular and diabetes mellitus pivotal drug trials according to year of drug approval.



https://doi.org/10.1161/JAHA.119.015594

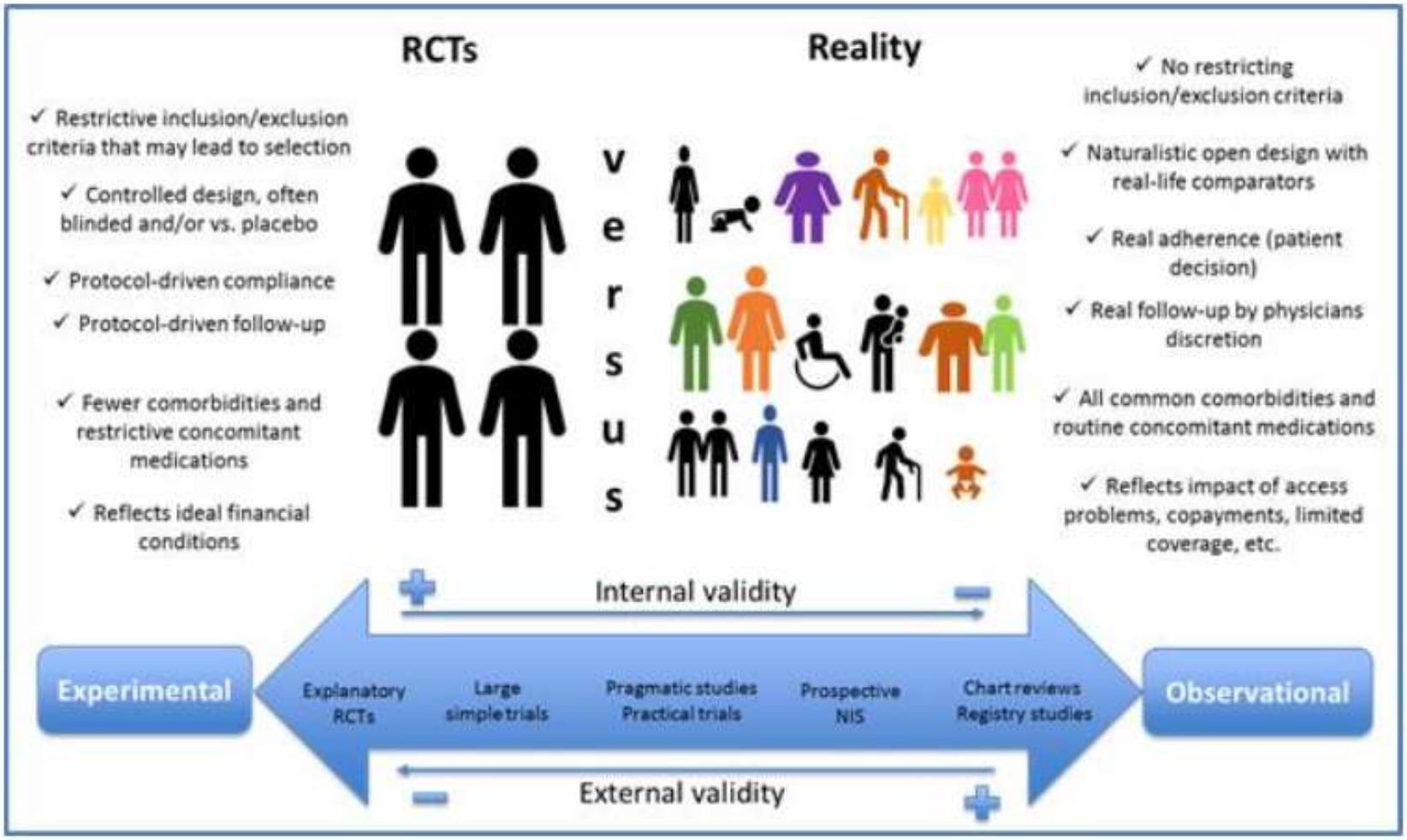
Comparison of overall percentage of whites and blacks enrolled in pivotal cardiovascular and diabetes mellitus drug trials according to year of drug approval.



https://doi.org/10.1161/JAHA.119.015594

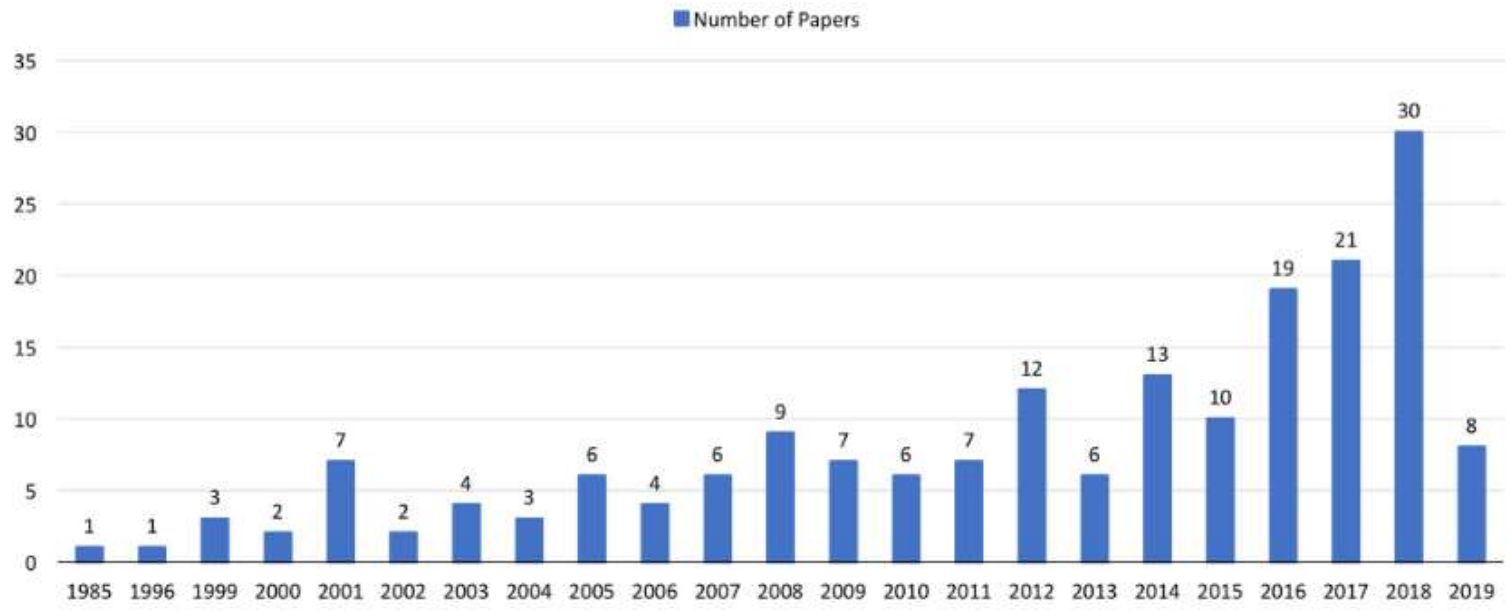
The Why of Diversity in Clinical Trials

- Generalizability
- Bias Reduction
- Federal Requirement per NIH for Phase III clinical trials (42 USC 289a-2) (AKA Mom's Rule.....)
- **Improve Health Equity**



chrome-extension://oemmndcbldboiebfnladdacbdfmadadm/https://www.neuroeconomix.com/wp-content/uploads/2019/05/Real-World-Evidence-in-healthcare-decision-making-Global-trends-and-case-studies-from-Latin-America.pdf

Generalizability Assessment Trends



Clin Transl Sci (2020) 13, 675–684; doi:10.1111/cts.12764

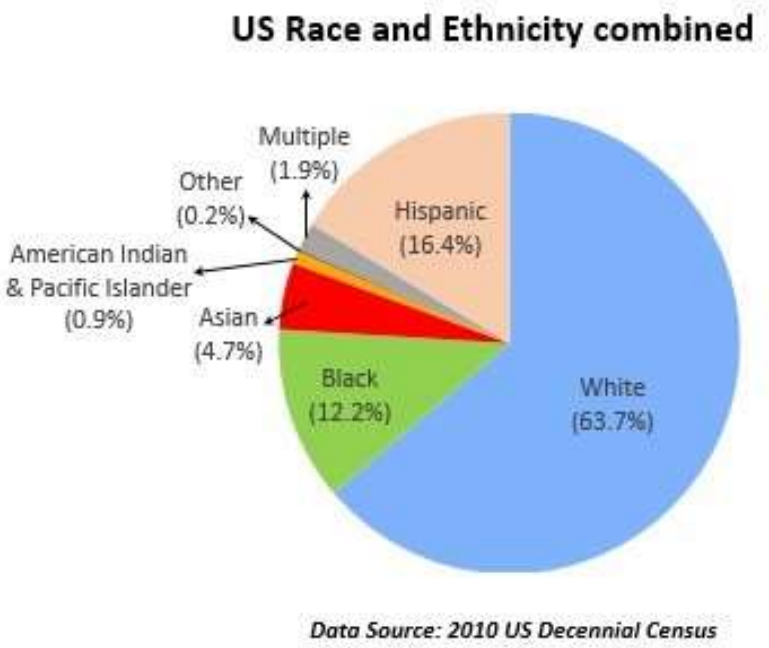
When is Enough Diversity Enough???

US Population vs. Global????

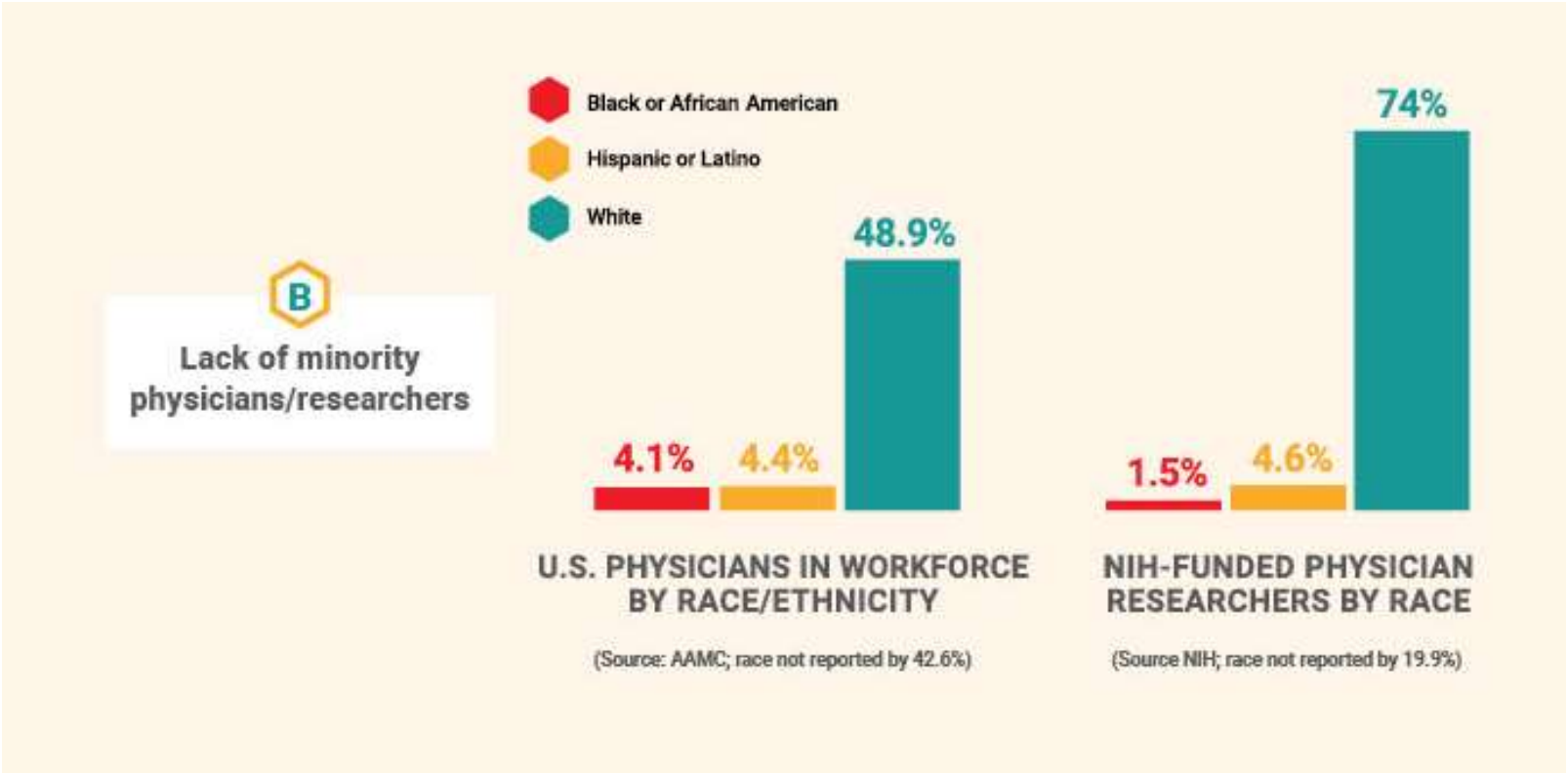
Definition of Diversity???

Pre-Defined Targets???

Type of Treatment???

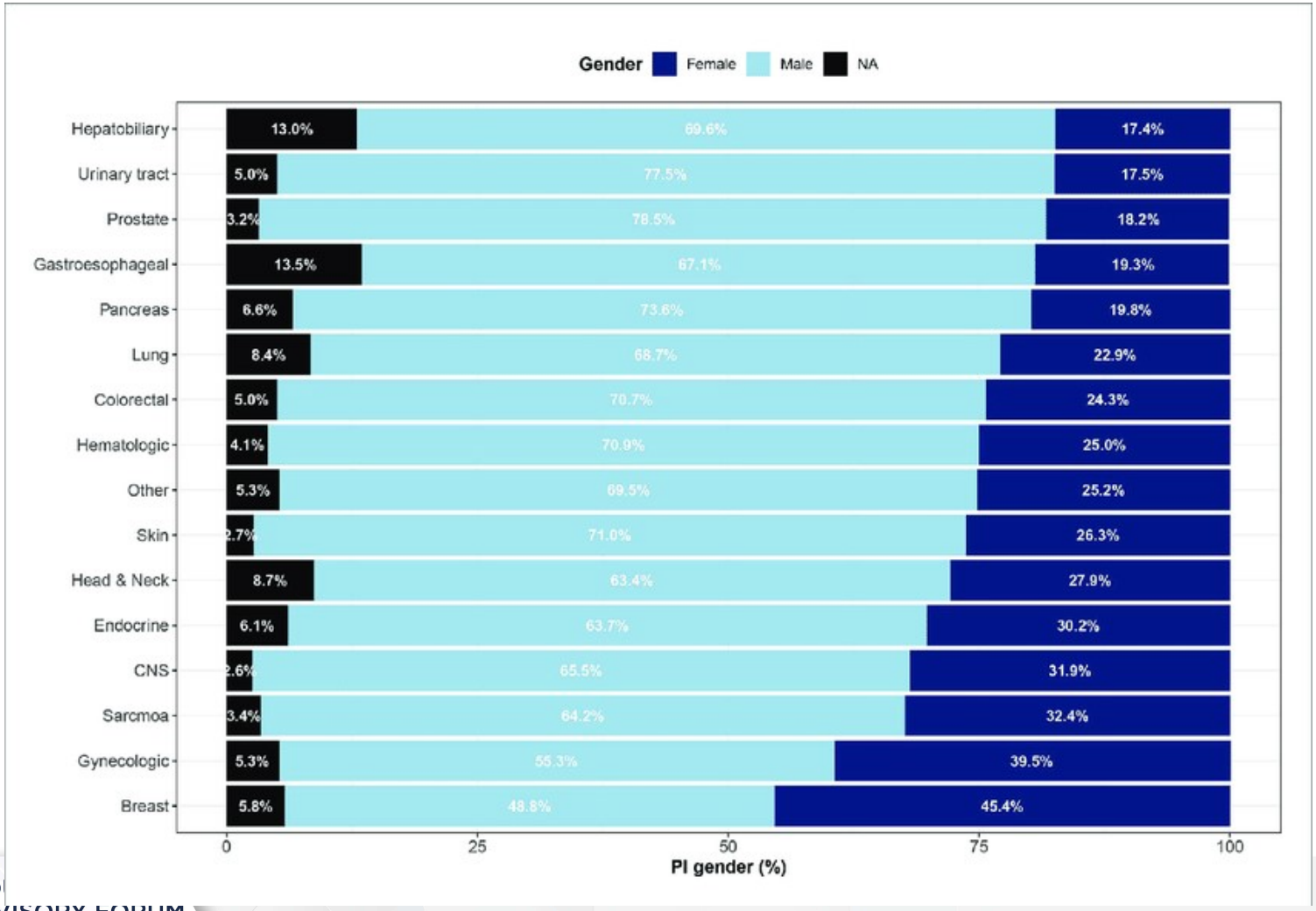


Investigator Diversity

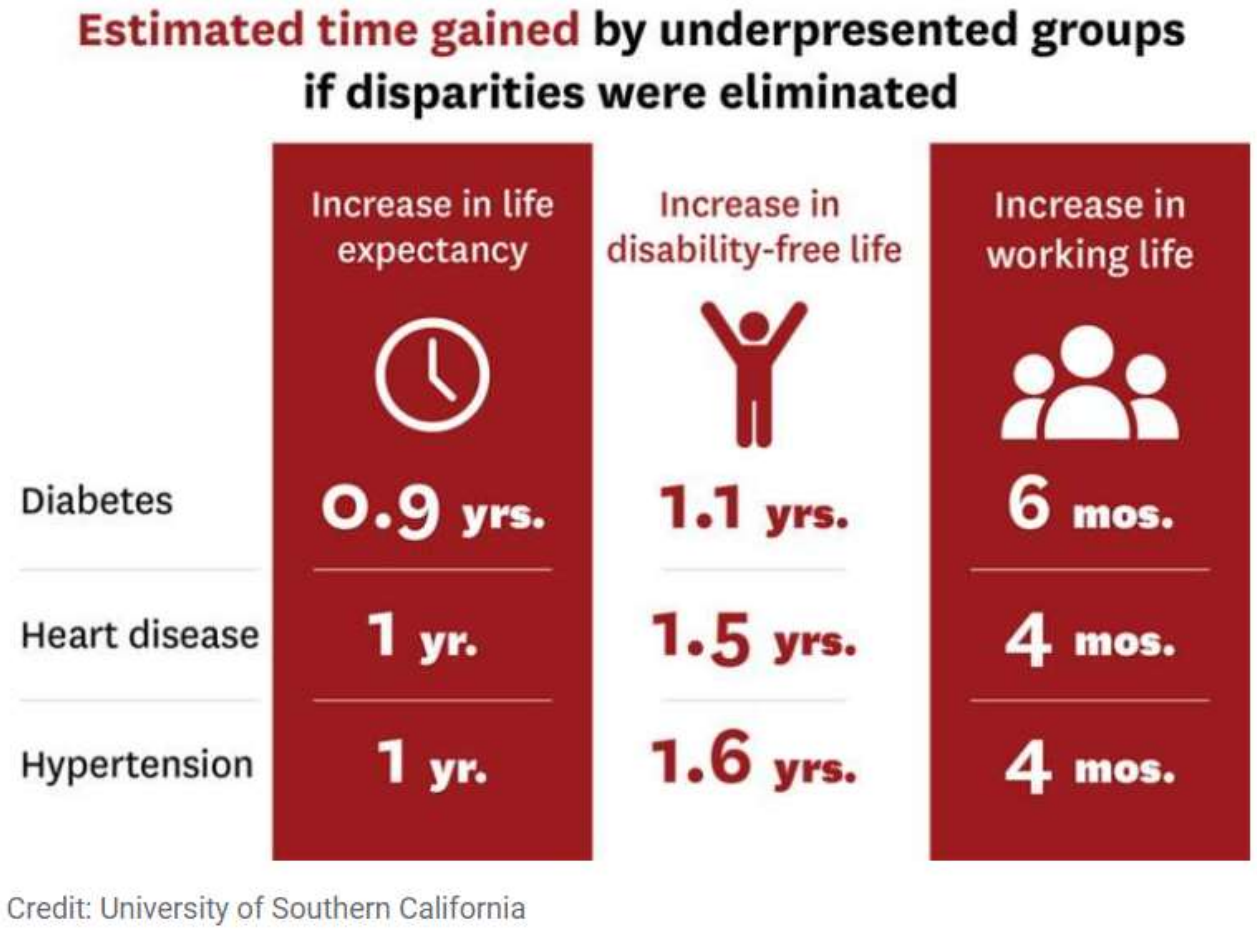


https://deep6.ai/resources/why-diversity-is-more-important-than-ever-for-clinical-trials/

Trends in Women's Leadership of Oncology Clinical Trials



https://www.frontiersin.org/articles/10.3389/fonc.2022.885275/full



Credit: University of Southern California

https://medicalxpress.com/news/2022-05-potential-problems-lack-diversity-clinical.html

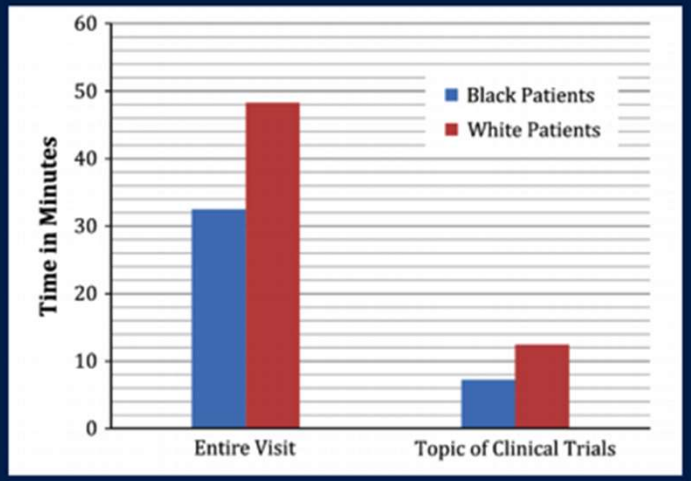
PHASES of a CLINICAL TRIAL

5 Critical Barriers to Minority Participation in Clinical Trials

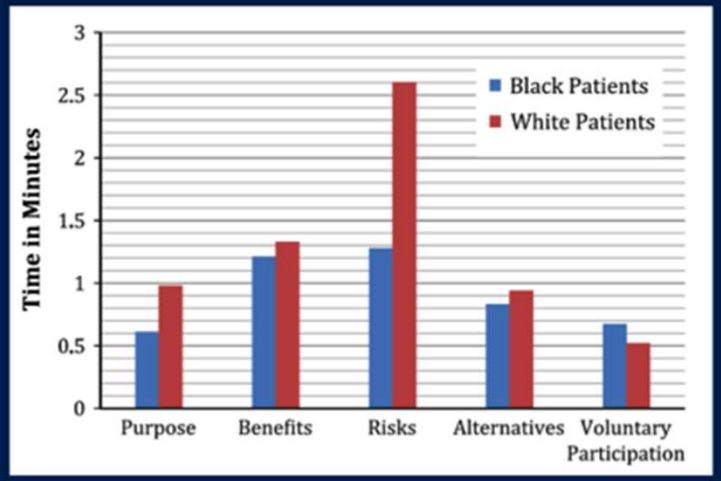
1. Mistrust
2. Lack of comfort with the clinical trial process
3. Lack of information about clinical trials
4. Time and resource constraints associated with clinical trial participation
5. Lack of clinical trial awareness

https://trialfacts.com/articles/diversity-inclusion/

Physicians talk to Black patients less than White patients.



Time spent talking with patients



Time spent talking about research consent

Eggly, S. *Health Expectations* 18.5 (2015): 1316-1326.

STRIDE
Strengthening Translational Research In Diverse Enrollment

University of Massachusetts Medical School
UMASS

UAB SCHOOL OF MEDICINE
Knowledge that will change your world

VANDERBILT UNIVERSITY
MEDICAL CENTER

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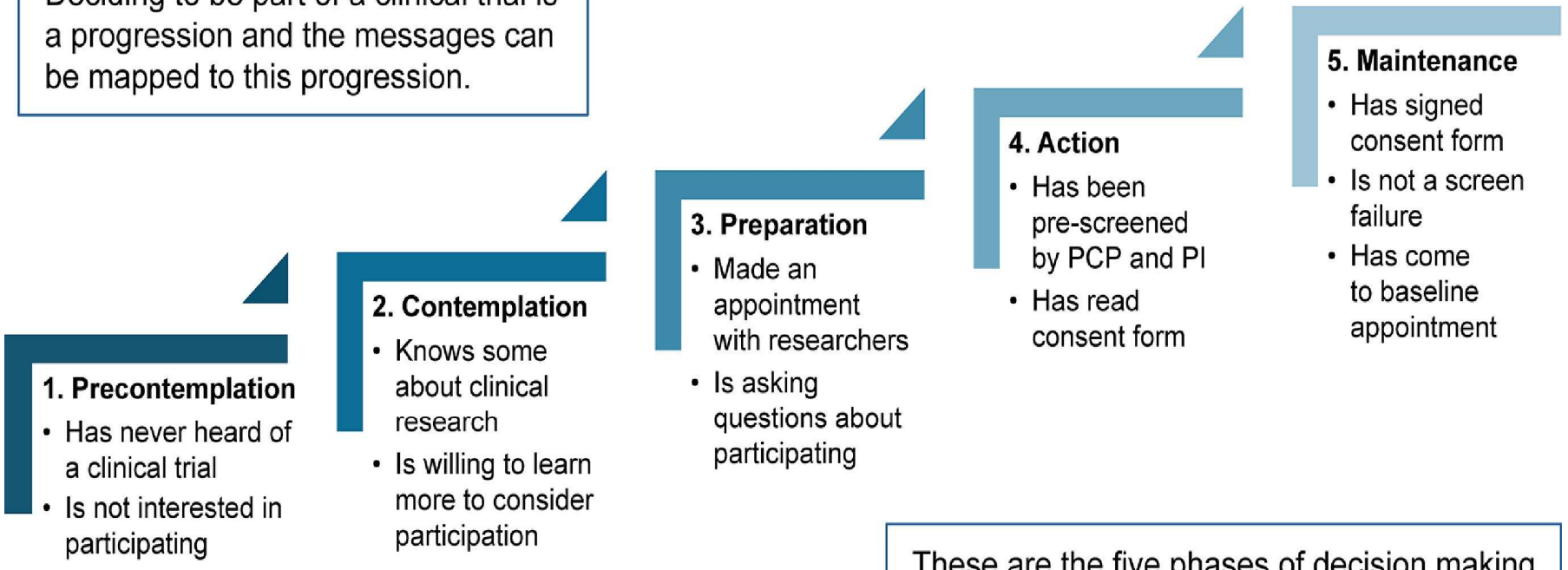
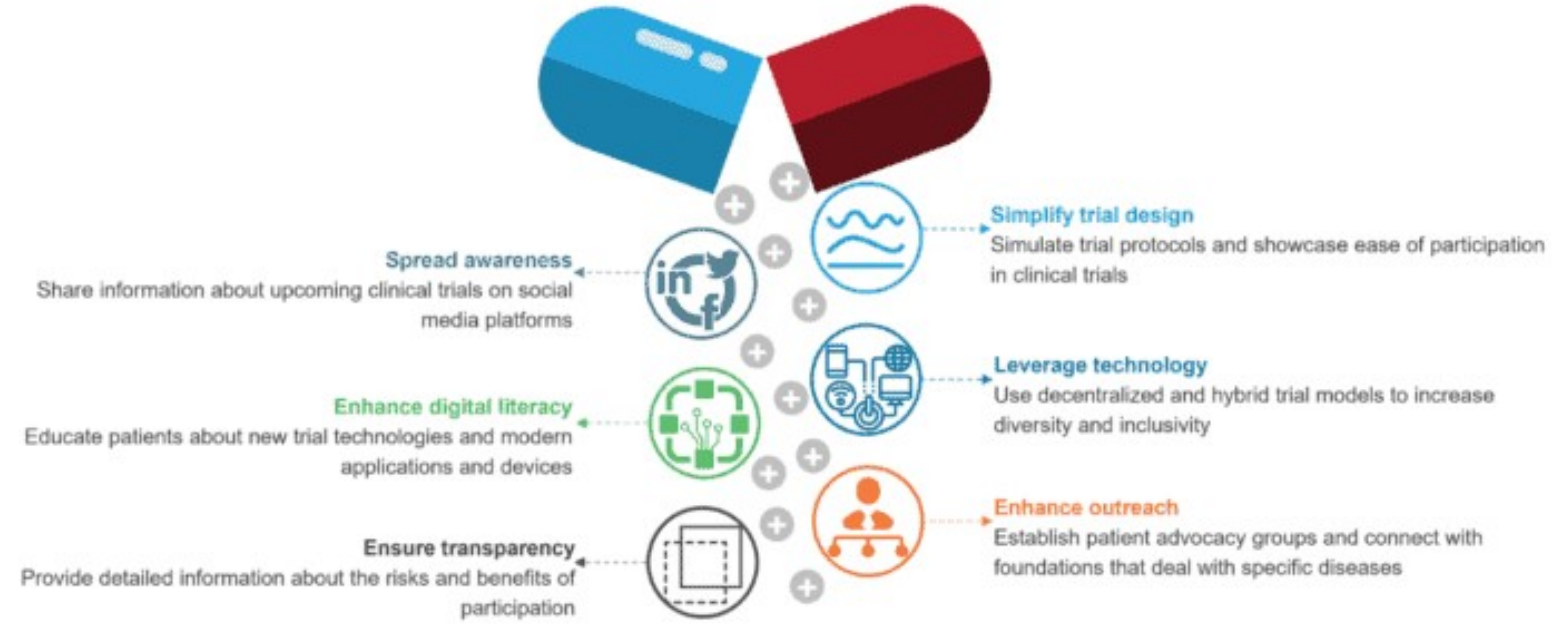
https://www.uab.edu/ccts/news-events/sept-ccts-forum-explores-the-challenge-of-increasing-diversity-in-clinical-trials

Deciding to be part of a clinical trial is a progression and the messages can be mapped to this progression.



These are the five phases of decision making in the transtheoretical model.

Initiatives to Address Patient Recruitment and Enrollment Challenges



Everest Group® Decentralized Clinical Trial Products PEAK Matrix® Assessment 2021

https://www.everestgrp.com/current-challenges-in-clinical-trial-patient-recruitment-and-enrollment/

Special Communication

March 23, 2022

Improving Enrollment of Underrepresented Racial and Ethnic Populations in Heart Failure Trials

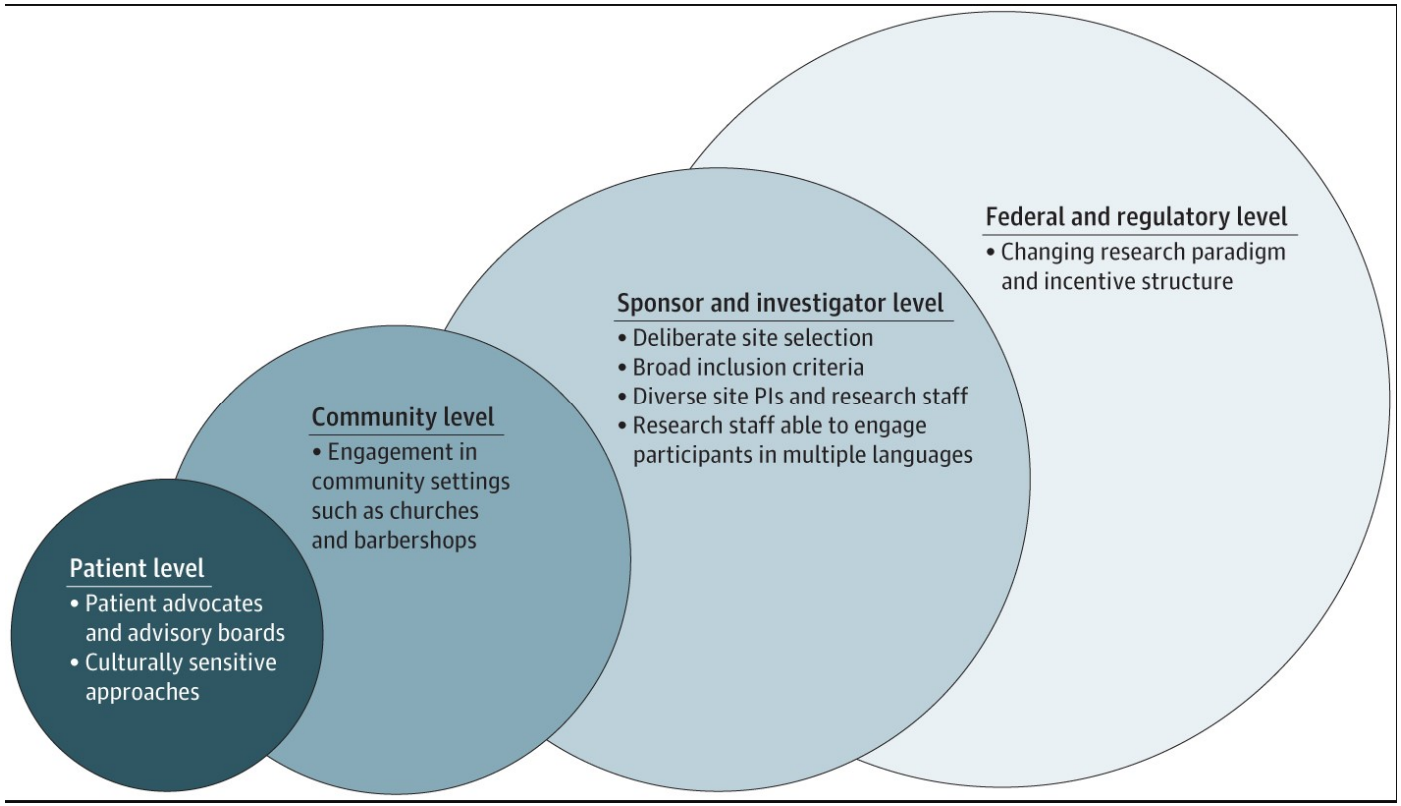
A Call to Action From the Heart Failure Collaboratory

Ersilia M. DeFilippis, MD[1]; Melvin Echols, MD[2]; Philip B. Adamson, MD, MSc[3]; Wayne B. Batchelor, MD, MHS[4]; Lauren B. Cooper, MD, MHS[4]; Lawton S. Cooper, MD, MPH[5]; Patrice Desvigne-Nickens, MD[5]; Richard T. George, MD[6]; Nasrien E. Ibrahim, MD[4]; Mariell Jessup, MD[7]; Dalane W. Kitzman, MD[8]; Eric S. Leifer, PhD[5]; Martin Mendoza, PhD[9]; Ileana L. Piña, MD, MPH[10]; Mitchell Psotka, MD, PhD[4]; Fortunato Fred Senatore, MD, PhD[11]; Kenneth M. Stein, MD[12]; John R. Teerlink, MD[13]; Clyde W. Yancy, MD, MSc[14,20]; JoAnn Lindenfeld, MD[15]; Mona Fiuzat, PharmD[16,17]; Christopher M. O'Connor, MD[4,16,17]; Orly Vardeny, PharmD, MS[18]; Muthiah Vaduganathan, MD, MPH[19]

» Author Affiliations | Article Information

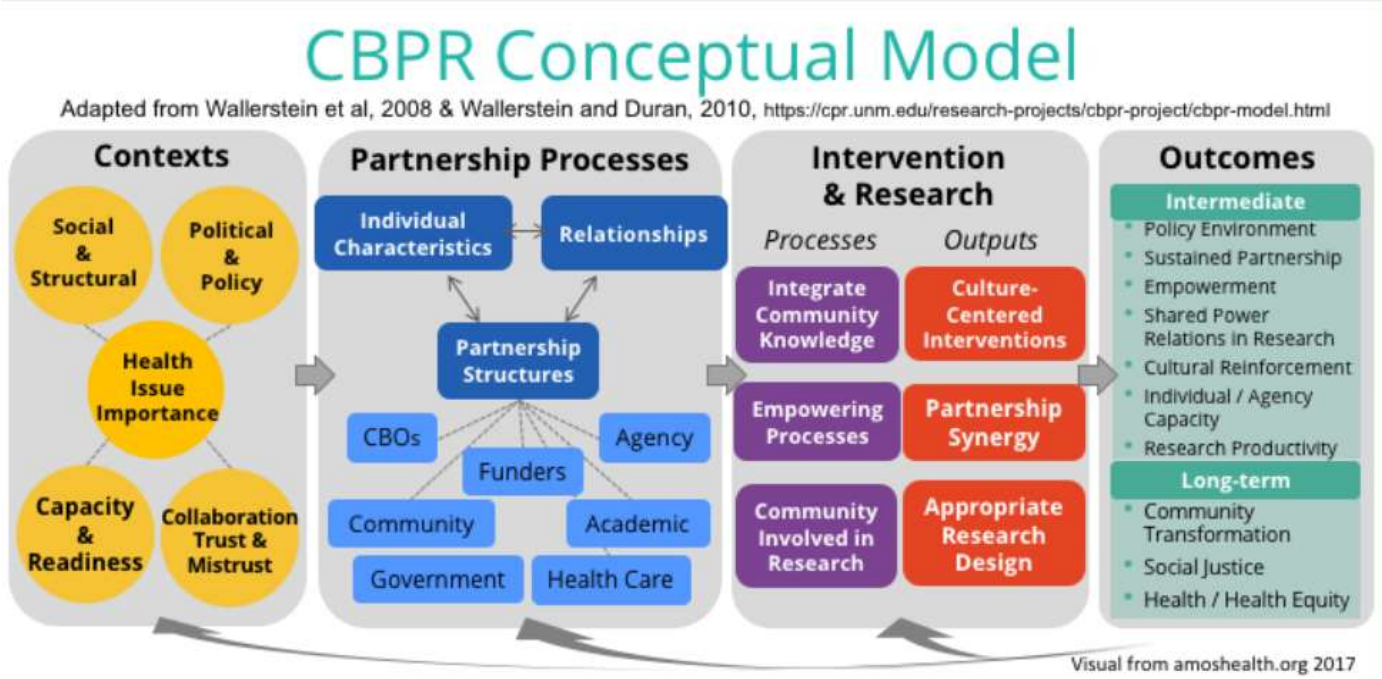
JAMA Cardiol. 2022;7(5):540-548. doi:10.1001/jamacardio.2022.0161

Effective Strategies



JAMA Cardiol. 2022;7(5):540-548. doi:10.1001/jamacardio.2022.0161

Community-Based Participatory Research for clinical trials???



https://crch.wvsom.edu/sites/default/files/2020-04/Strategies%20and%20Models%20for%20CBPR.pdf

CBPR and RCTs

- Patients want to know the results of the trial!!!!
- More focus on patient values and non-pressure tactics of recruitment
- More commitment from industry-sponsored trials to support access of medication to ALL patients in high enrolling or active sites (+ studies)
- Constant assessment of patient satisfaction across clinical trial portfolio

Changing the Research Paradigm

- Efforts supported by professional societies and guideline statements
- Site PI mentorship programs
- Deliberate site selection by sponsors
- Motivated Site Principal Investigators

Cardiovascular Clinical Trial Equity

- Diverse representation in clinical trials, all things considered, allows us to determine how effective treatments are in a real-world setting

- Innovative strategies, including funding, are important to increase clinical trial diversity.

- Go where the patients are!!! (Region and Sites)

We Thank You…..

ACC Registries and Other Vehicles for Patient Diversification

Panel Discussion- Moderated by Melvin Echols, MD, FACC

- **Jeptha Curtis, MD, FACC** - NCDR optimization
- **Rajesh Dash, MD, PhD, FACC** - Update on HealthPals and Veradigm capabilities
- **Ty Gluckman, MD, FACC** – Approaches to different trial designs
- **Jennifer Mieres, MD, FACC** – How will journals consider trial diversity now and in the future?
- **Kendal Whitlock –** Walgreens perspective
- **Rafael Cavalcante, MD, PhD** – Boston Scientific perspective

Jeptha Curtis, MD, FACC

NCDR Optimization

CLINT™

by HealthPals

A novel solution to optimize Diversity and Inclusion in Clinical Trials

Cardiovascular Clinical Drug Development: ~$2B per compound

Ideally, trials will rapidly recruit…

- Patients who are eligible & interested
- Patients who are likely to finish the study
- Cohorts that will reach endpoints quickly
- Cohorts that mirror demographic distribution of disease prevalence

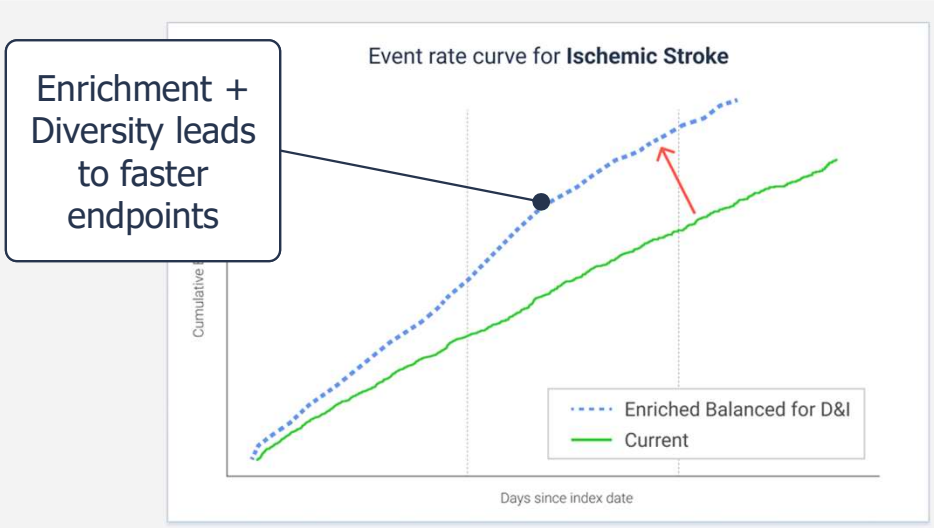
In **reality**…

- 86% of RCTs fail to hit target recruitment
- ~50% of sites recruit 0-1 patients
- Time to market is delayed
- The FDA Diversity & Inclusion mandate will make trial recruitment even more difficult

CLINT optimizes Diversity and Inclusion in protocol design and recruitment

Protocol Design with D&I Balance

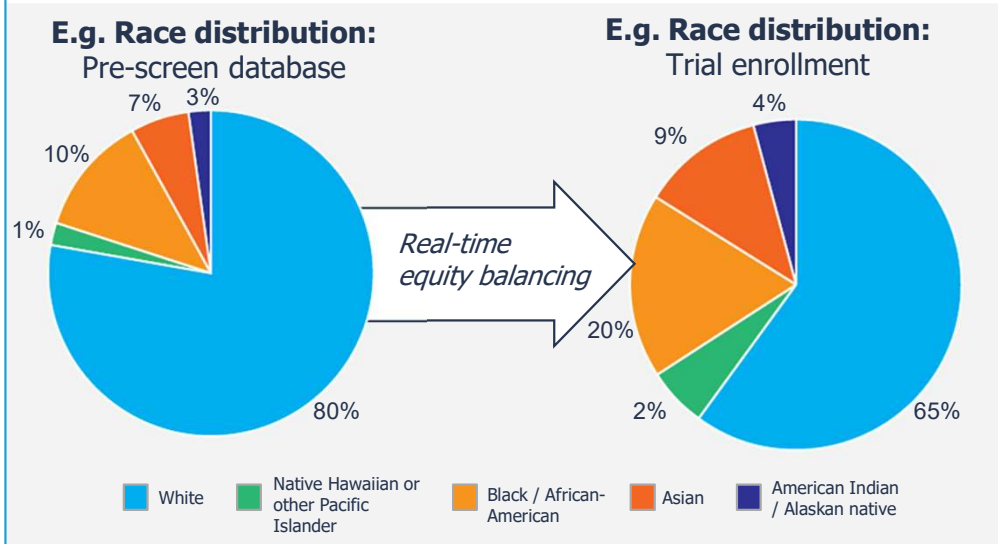
Reach endpoints faster



CLINT *Identify* **optimizes** the patient pool and diversity for maximal event separation

Recruitment

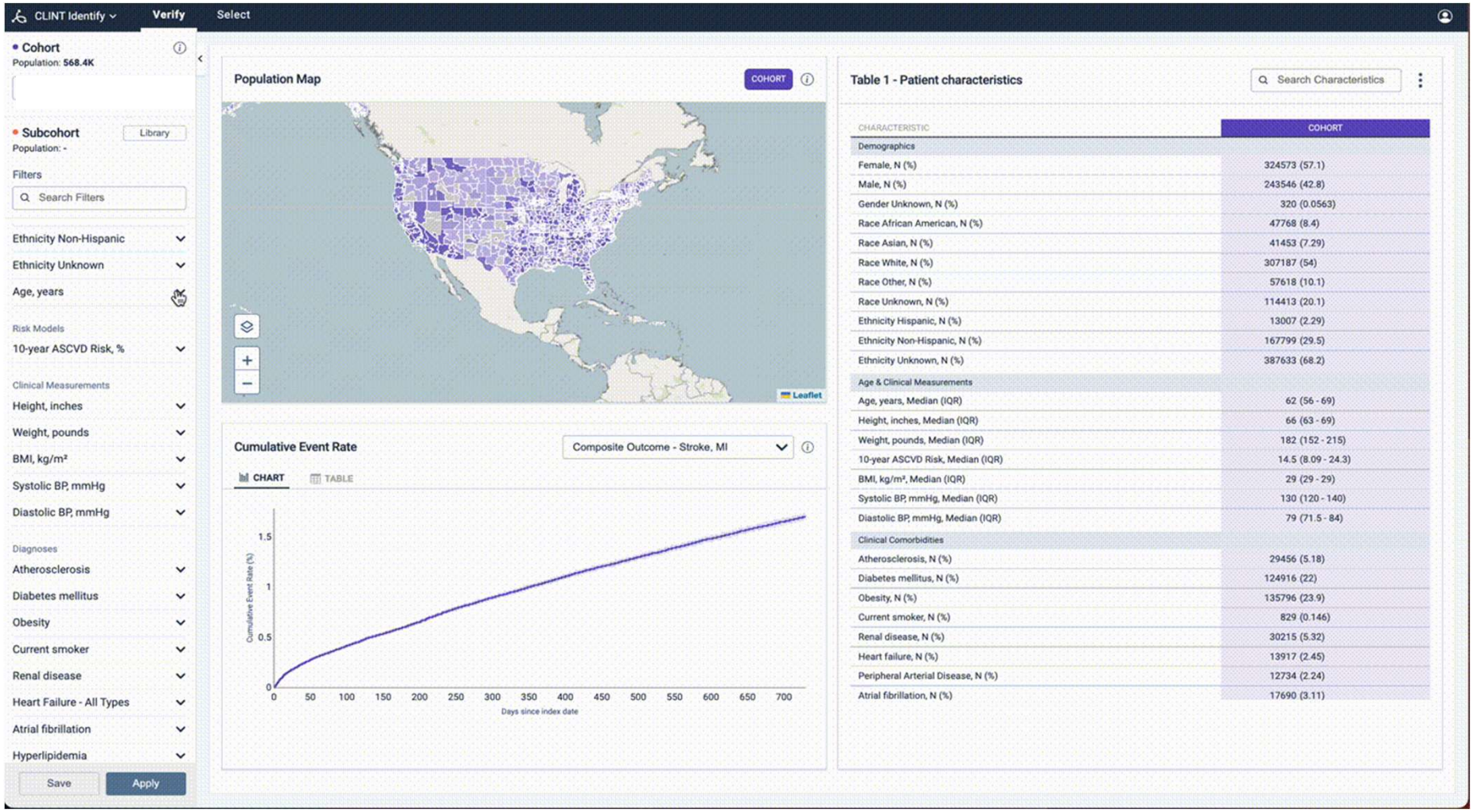
Achieve D&I targets in real-time



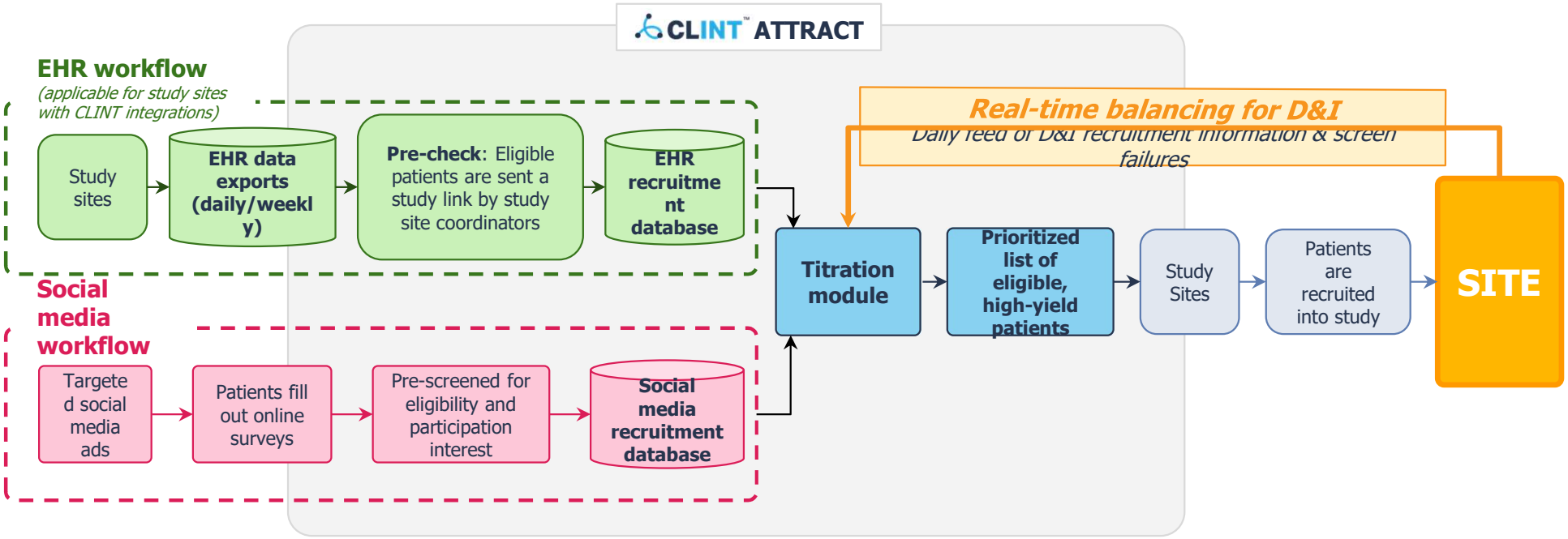
CLINT *Attract* **prioritizes** underrepresented groups for trial screening at each site

Protocol Design

CLINT *Identify* - Designing for D&I



CLINT *Attract* drives diverse patient recruitment



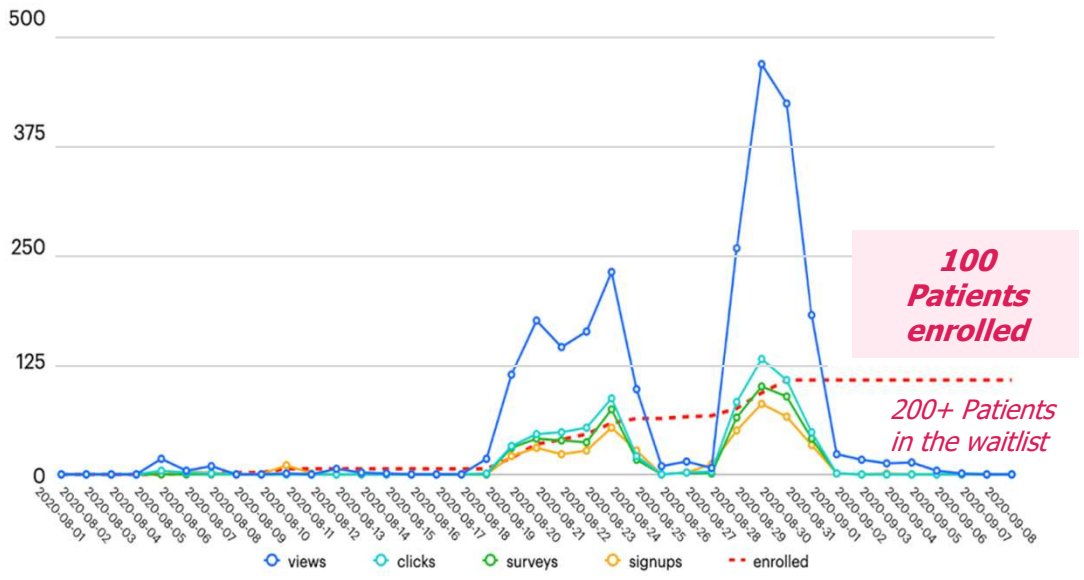
CLINT *Attract* cuts recruitment time in half, increases enrollment yield 3-5X while significantly reducing screen failures

Case Study: DeTAP trial *(Decentralized Trial in Afib Patients)*

1. **Accelerate and scale** recruitment through hyper-targeting of eligible patients
2. **Enrich** the recruitment cohort to high-degrees of eligibility for high conversion rates for referrals to randomization

***CLINT Attract* RECRUITMENT STRATEGY**	TRADITIONAL RECRUITMENT
94 Patients Enrolled **12 Days**	6 Patients Enrolled 28 Days

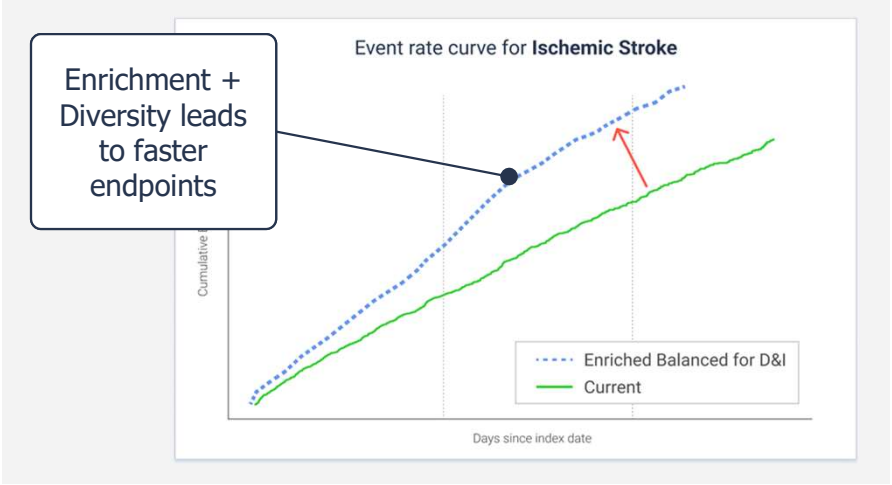
CLINT™ Subject recruitment and enrichment module:

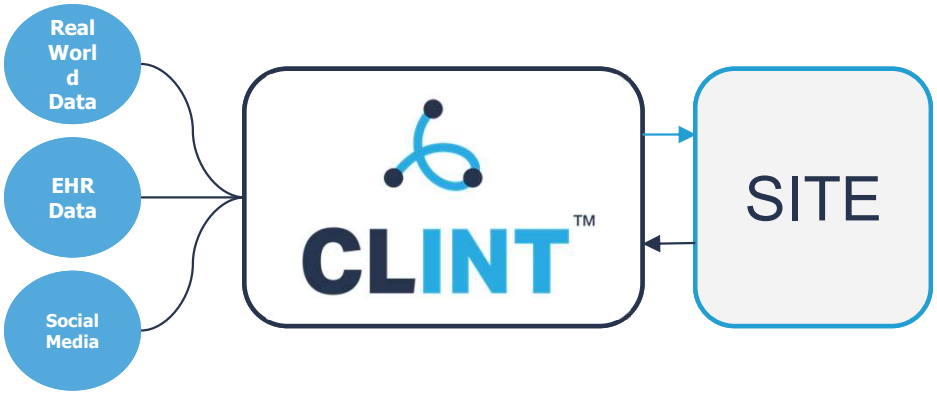


Protocol design

Recruitment

Summary





CLINT *Identify* = Protocol Success

- Identifies a diverse, enriched-risk patient pool
- Identifies sites with abundant diverse patients
- Trial team can quickly validate protocol amendments

CLINT *Attract* = Recruitment Success

- Focused patient recruitment: SM + EHR direct
- Fully screens patients for eligibility + interest
- Prioritizes referred patients for D&I

Thank You

Recent publications & whitepapers, in collaboration with:

REAGAN-UDALL FOUNDATION for the Food and Drug Administration

Janssen

veradigm

AMERICAN COLLEGE of CARDIOLOGY

healthpals.ai

Diversifying Patients in Clinical Trials—Approaches to Different Trial Designs

Ty J. Gluckman, MD, MHA, FACC, FAHA, FASPC

Medical Director, Center for Cardiovascular Analytics, Research, and Data Science (CARDS)

Providence Heart Institute

Providence St. Joseph Health

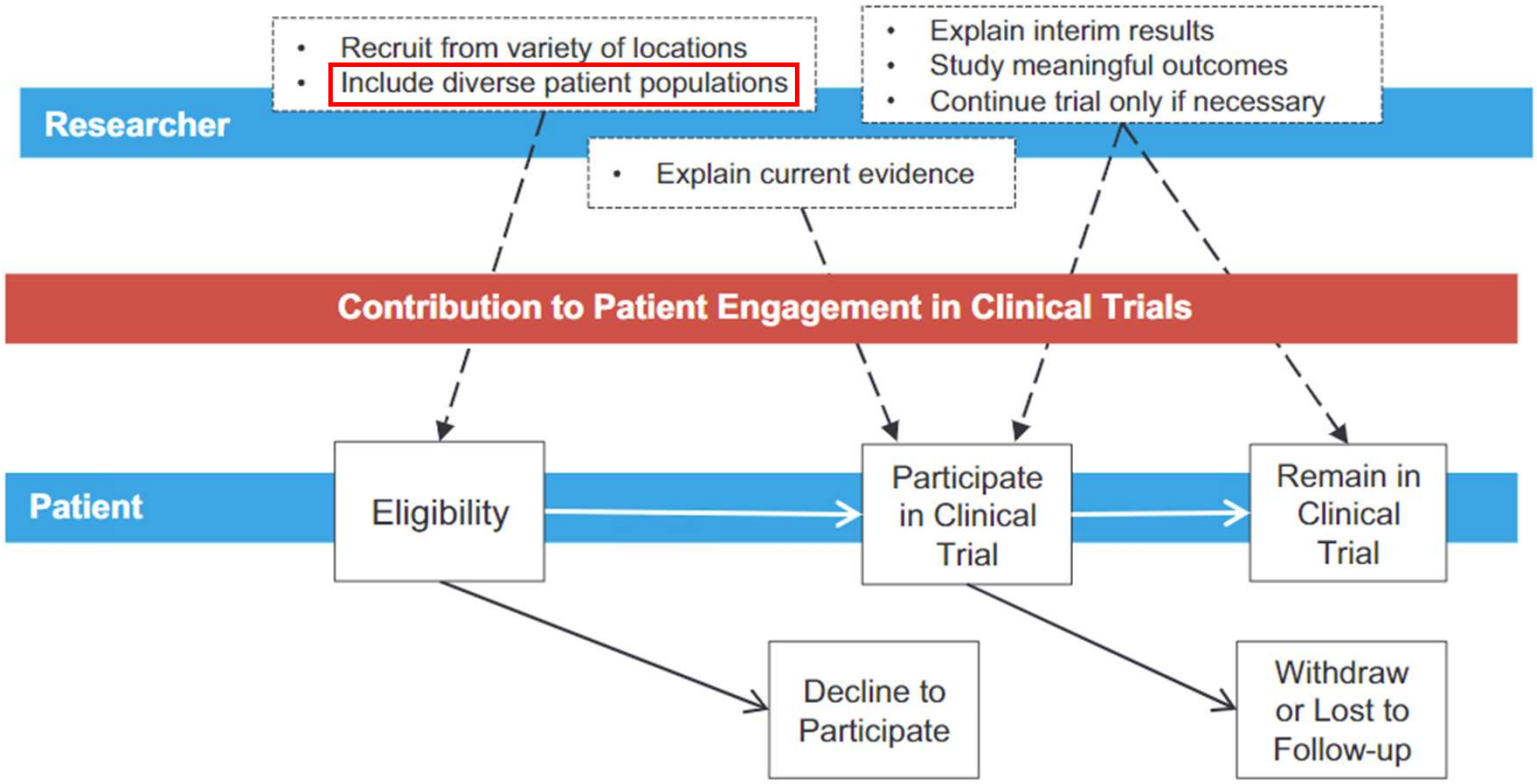
Portland, Oregon

What are We Really Talking About?

"Because people may experience the same disease differently, it is essential that clinical trials include people with a variety of lived experiences and living conditions, as well as characteristics like race and ethnicity, age, sex, and sexual orientation, so that all communities benefit from scientific advances."

National Institute on Minority Health and Health Disparities. https://www.nimhd.nih.gov/resources/understanding-health-disparities/diversity-and-inclusion-in-clinical-trials.html. Accessed December 4, 2022

Patient Engagement in Clinical Trials



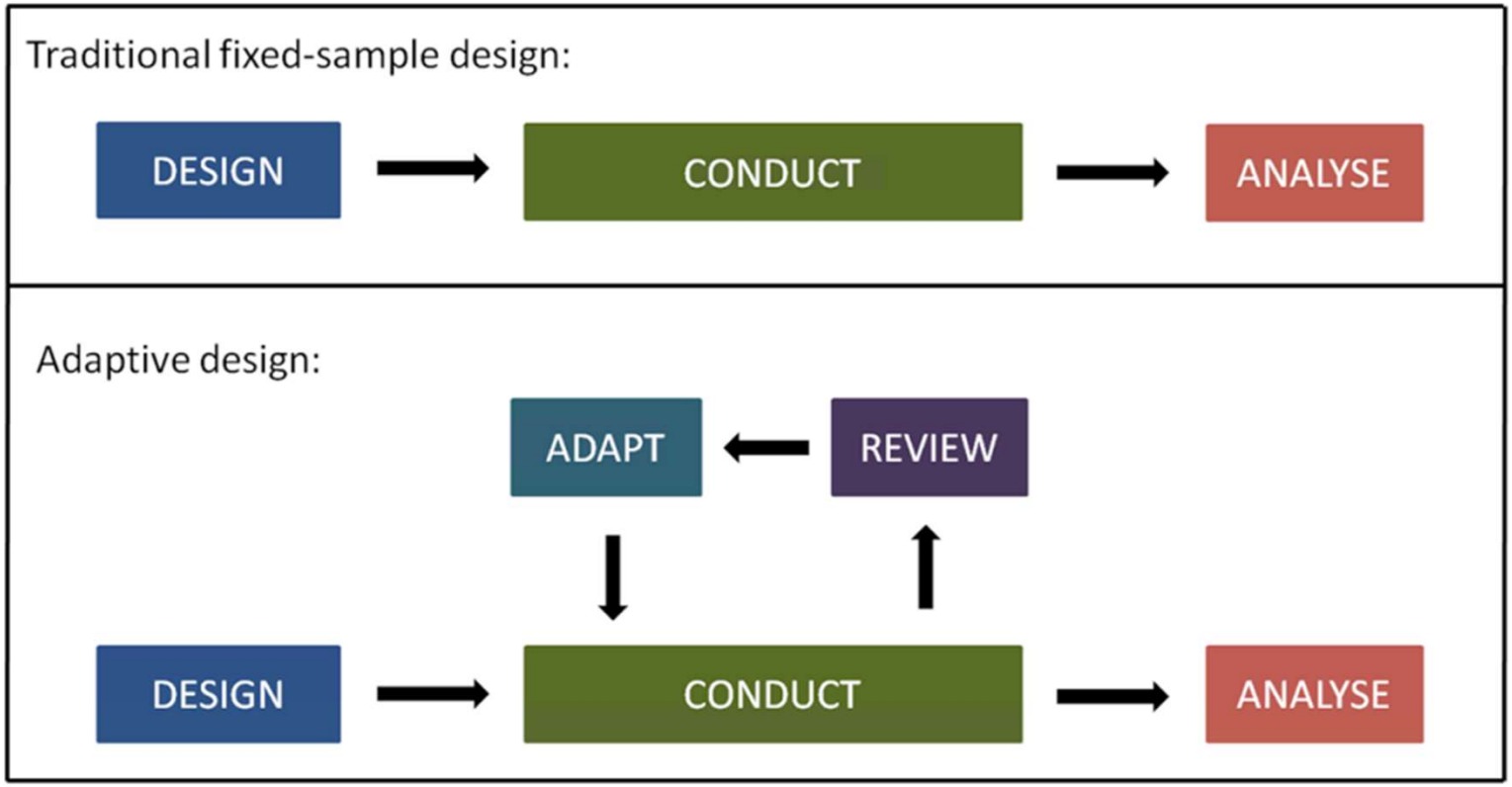
Mullins CD et al. Value in Health 2014;17:471-475

Increasing Diversity in Clinical Trials

- Inclusive trial practices
  - Cultural competency training
  - Community partnerships
  - Personalized approach
  - Multilingual materials and staff
  - Communication-specific strategies
  - Increasing understanding and trust
  - Tackling logistical barriers
- Broadening eligibility criteria
- Using less traditional trial designs
  - Adaptive clinical trials
  - Pragmatic clinical trials
  - Aligned clinical trials
- Other tactics
  - Making participation less burdensome
  - Enrollment and retention practices
  - Expanded access

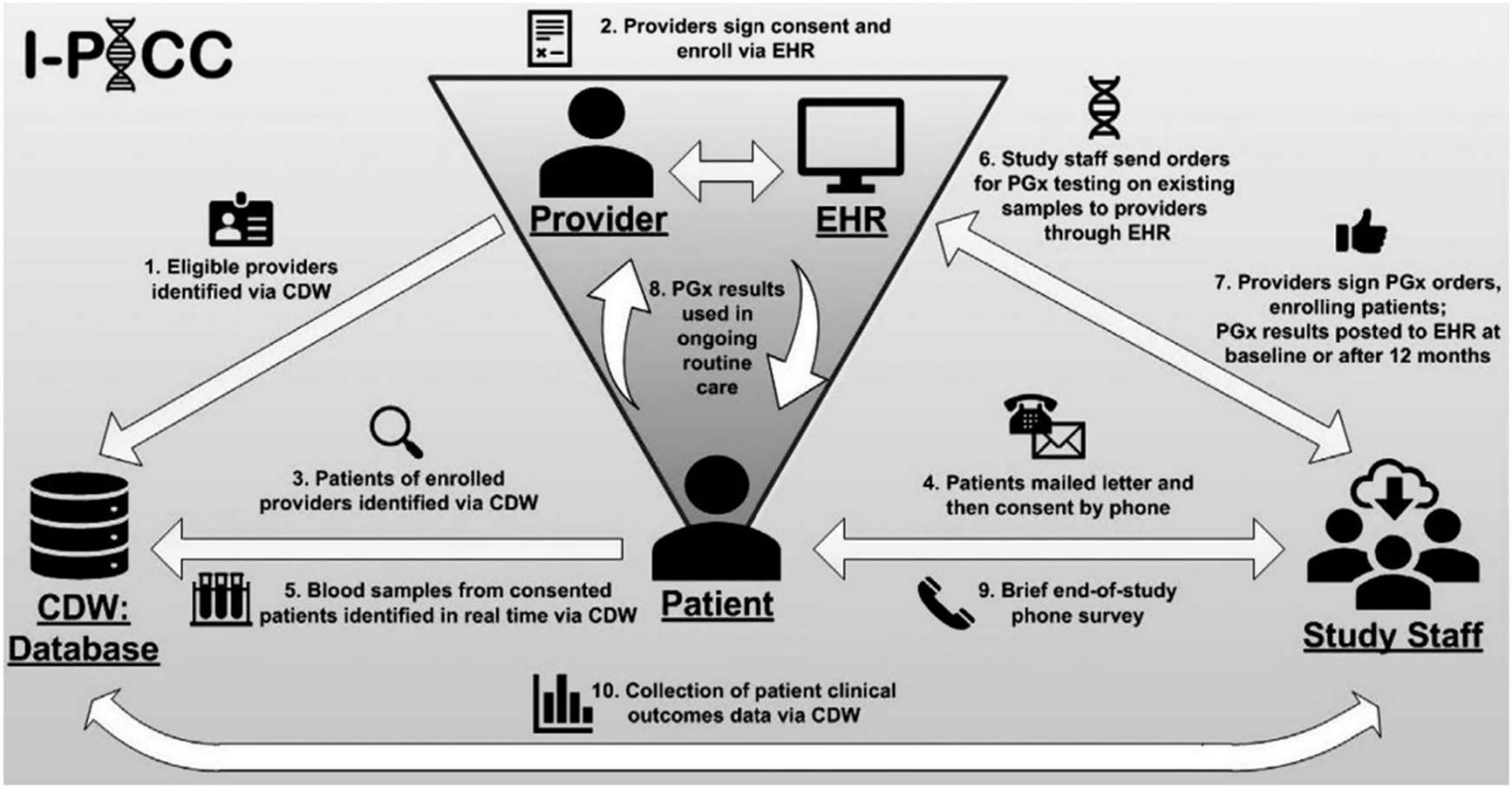
FDA. https://www.fda.gov/media/127712/download. Accessed December 5, 2022;
Bodicoat DH et al. Trials 2021;22:880-891

Adaptive Clinical Trials



Pallman P et al. BMC Medicine 2018;16:29-44

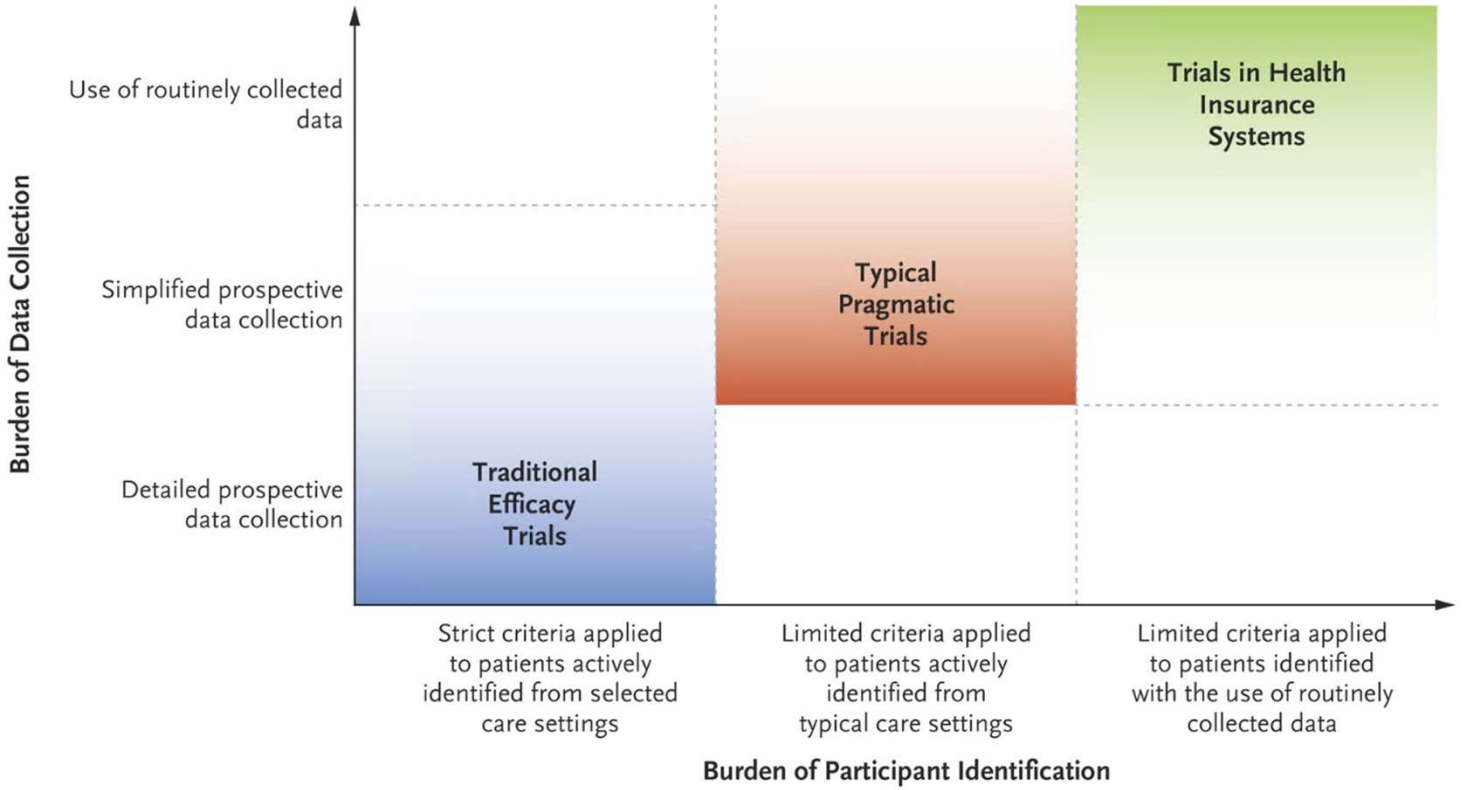
Pragmatic Clinical Trials—Typical



PGx = pharmacogenomic

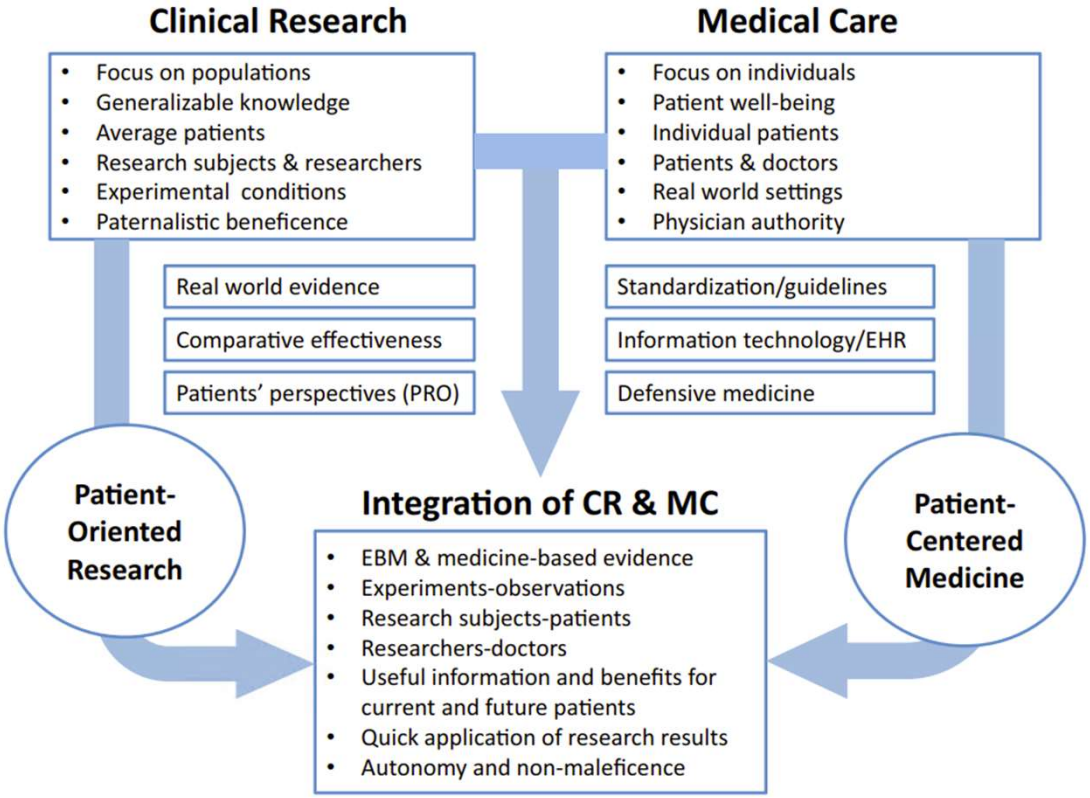
Brunette CA et al. Clin Transl Sci 2020;13:381-390

Pragmatic Clinical Trials—Less Typical



Choudhry NK. N Engl J Med 2017;377:957-964

Aligning Clinical Trials with Clinical Care



Sacristan JA. BMC Medical Research Methodology 2015;15:4-11

It Takes a Village

American College of Cardiology. https://www.cardiosmart.org/topics/manage-your-care/assets/infographic/clinical-research-including-everyone-matters. Accessed December 5, 2022

Jennifer Mieres, MD, FACC

How will journals consider trial diversity now and in the future?

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Kendal Whitlock

Walgreens

Rafael Cavalcante, MD, PhD

Boston Scientific

Trial Participation Diversity

- How are industry partners prioritizing diversity in clinical trials? What is working most effectively?
- How can industry/ ACC /medical societies invest in sustainable collaborations to improve care and outcomes in under-resourced communities / communities with unmet medical needs?
- What goals should ACC and its industry partners set in the short and long term around diversifying clinical trial recruitment?

The ACC Thanks You For Your Partnership!

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