

# Practical Approaches to Improving Diversity in Clinical Trials

Wednesdays

11AM - 12noon ET



**MULTI-REGIONAL  
CLINICAL TRIALS**

THE MRCT CENTER of  
BRIGHAM AND WOMEN'S HOSPITAL  
and HARVARD

## LEARNING IN: A WEBINAR SERIES

# Disclaimer

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<b>Recording available</b>	Community Awareness, Access, Knowledge
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<b>Recording available</b>	Study Conduct (Recruitment, Retention)
<b>Recording available</b>	Data Standards and Analysis
<b>January 27, 2021</b>	Stakeholder Roles and Responsibilities
<b>February 10, 2021</b>	Role of Data in Diversity: Genetics & Real World Data



## Stakeholder Roles and Responsibilities

January 27, 2021  
11AM - 12noon ET

### RADM Richardae Araujo Moderator

Associate Commissioner for  
Minority Health Director of the  
Office of Minority Health and Health Equity,  
U.S. Food and Drug Administration (FDA)



### David H. Strauss, MD Moderator

Special Lecturer,  
Columbia University  
Vagelos College of Physicians and Surgeons  
Senior Advisor, MRCT Center



### Fabian Sandoval, MD Guest Speaker

CEO & Research Director,  
Emerson Clinical Research Institute, Inc.  
Leadership Council Member Society  
for Clinical Research Sites,  
Emmy Winning Host "Tu Salud Tu Familia"  
and Medical Contributor Telemundo  
Washington D.C.



### Chris Reddick, MD Guest Speaker

Vice President,  
Head of R&D Health Equity,  
Center for Health Equity & Patient Affairs,  
Takeda Pharmaceuticals



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# **Addressing Diversity in Clinical Research: Stakeholder Roles, Responsibilities and Accountability**

**David H. Strauss, MD\***

**\*MRCT Center of BWH & Harvard  
and Columbia University Vagelos College of  
Physicians and Surgeons**

**January 27, 2021**

# The Multi-Regional Clinical Trials Center (MRCT Center)

## Our Vision

Improve the integrity, safety, and rigor of global clinical trials.

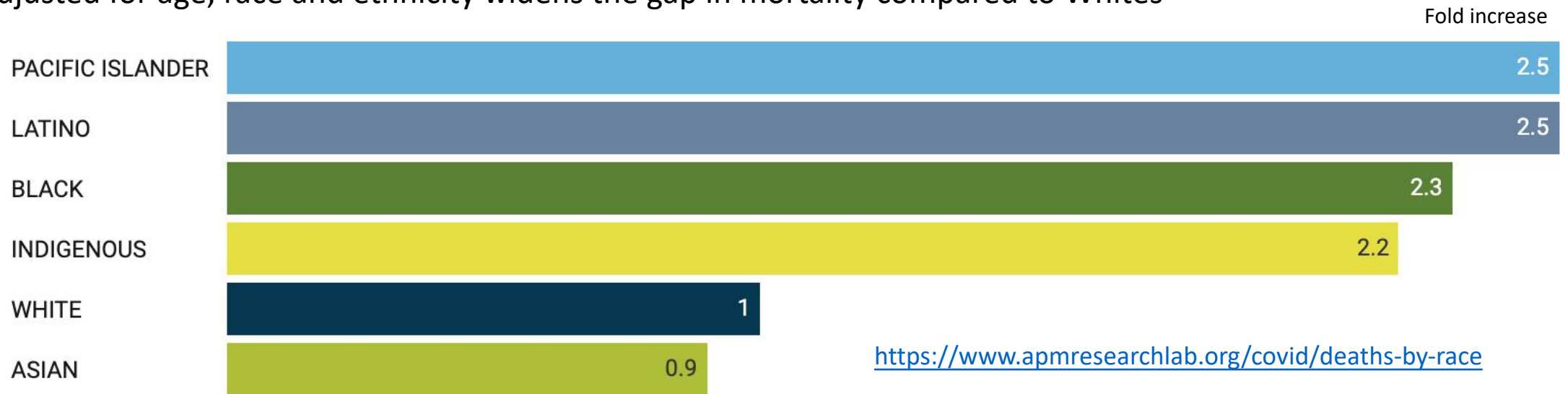
## Our Mission

Engage diverse stakeholders to define emerging issues in global clinical trials and to create and implement ethical, actionable, and practical solutions.



# Health disparities by race and ethnicity in the COVID-19 pandemic

Adjusted for age, race and ethnicity widens the gap in mortality compared to Whites



<https://www.apmresearchlab.org/covid/deaths-by-race>

## But remain underrepresented in research



The NEW ENGLAND  
JOURNAL of MEDICINE

Perspective  
AUGUST 27, 2020

### Racial Disproportionality in Covid Clinical Trials

Daniel B. Chastain, Pharm.D., Sharmon P. Osae, Pharm.D., Andrés F. Henao-Martínez, M.D.,  
Carlos Franco-Paredes, M.D., M.P.H., Joanna S. Chastain, Pharm.D., and Henry N. Young, Ph.D.

News & Analysis

Medical News & Perspectives

### Researchers Strive to Recruit Hard-Hit Minorities Into COVID-19 Vaccine Trials

Mary Chris Jaklevic, MSJ

<https://jamanetwork.com/journals/jama/fullarticle/2769611>



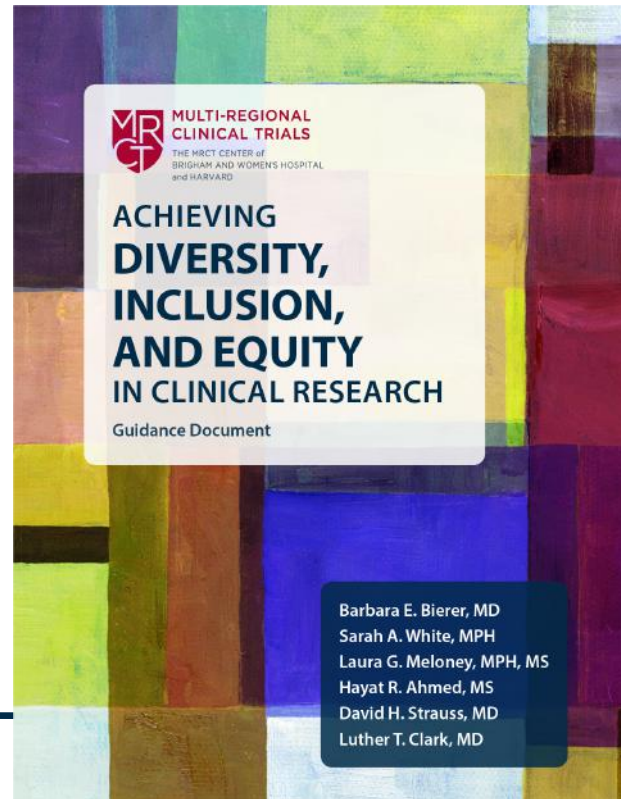
# Leadership and Guidance

- RADM Richardae Araojo, PharmD, MS, U.S. FDA
- Barbara E. Bierer, MD, MRCT Center
- Luther T. Clark, MD, Merck & Co., Inc.
- Milena Lolic, MD, U.S. FDA
- David H. Strauss, MD, Columbia University
- Sarah White, MPH, MRCT Center

## MRCT Center staff:

- Carmen Aldinger, PhD, MPH
- Hayat Ahmed, MS
- Laura Meloney, MS, MPH
- Joshua Smith-Sreen, MBE

## Achieving Diversity, Inclusion, Equity In Clinical Research



And the invaluable contributions of >50 workgroup members, representing:

- Patients, Patient Advocates
- Academia
- Pharmaceutical companies
- CROs
- Non-profit organizations
- Trade associations
- Government agencies
- Research institutes

Each serving in their individual capacity.



# Guidance Document

- The product of the contributions and consensus of a diverse, multi-stakeholder working group
- Provides practical and actionable recommendations
- ***Accountability section considers how each stakeholder can change the paradigm***
- Toolkit consolidates unique and adaptable resources



# Inclusion: a matter of both scientific importance and social responsibility

- Analyses of group differences in safety and efficacy among diverse populations can promote identification of both underlying biological factors and socially relevant factors that affect health, the “social determinants of health” (Beneficence)
- Seeks fairness in the distribution of the benefits of research (Justice)
- Builds public trust in research and healthcare



# Stakeholder Responsibilities



- Understanding the Case for Diversity
- Ownership
- Collaboration/interaction

# Altering the Landscape

**Tracking  
Diversity**

**Transparency**

**Accountability**

# Four Cross-cutting Responsibilities

1. Establish diversity as an organizational priority
2. Make public commitments to diversity
3. Incorporate patient and community perspectives
4. Create expectations for others along the research pathway



# 1. Establishing diversity as an organization priority, some examples:

- Establish diversity, inclusion, and equity as an organizational priority and core value
- Commit to diversity by setting research priorities, providing training and allocating resources to address the needs of understudied and underrepresented populations
- Create positions (or roles) tasked with promoting diversity, ensure adequate resource allocation, and build infrastructure to facilitate communication across component functions
- Create organization-wide performance standards, metrics, and incentives that encourage and reward progress toward diversity's goals
- Capture specific metrics relating to diverse enrollment, including geographic diversity, underrepresented minority populations (e.g., race, ethnicity, sex, young and elderly, etc.) and other understudied populations.



## 2. Making public commitments to diversity

“

*The safety and efficacy of medical treatments are assessed primarily by clinical research; such research should reflect the population for whom the treatment is intended. [The organization] is committed to inclusion of diverse populations, including people of varying age, race, ethnicity, sex, gender, and other potential effect modifiers, to better reflect the population for whom the treatment is intended, in order to advance better health outcomes for all.*

”

### 3. Incorporate patient and community perspectives

Allow the patient perspective to influence research priorities and reframe research questions



Invite the patient and community into the organization in key leadership roles, as advisors, and as consultants to increase organizational accountability

Seek patient and community input to tailor study design and implementation to improve access, enrollment, and retention



# 4. Create expectations for others along the research pathway

Industry



Contract Research Organizations



Sites



Investigators-Grantees



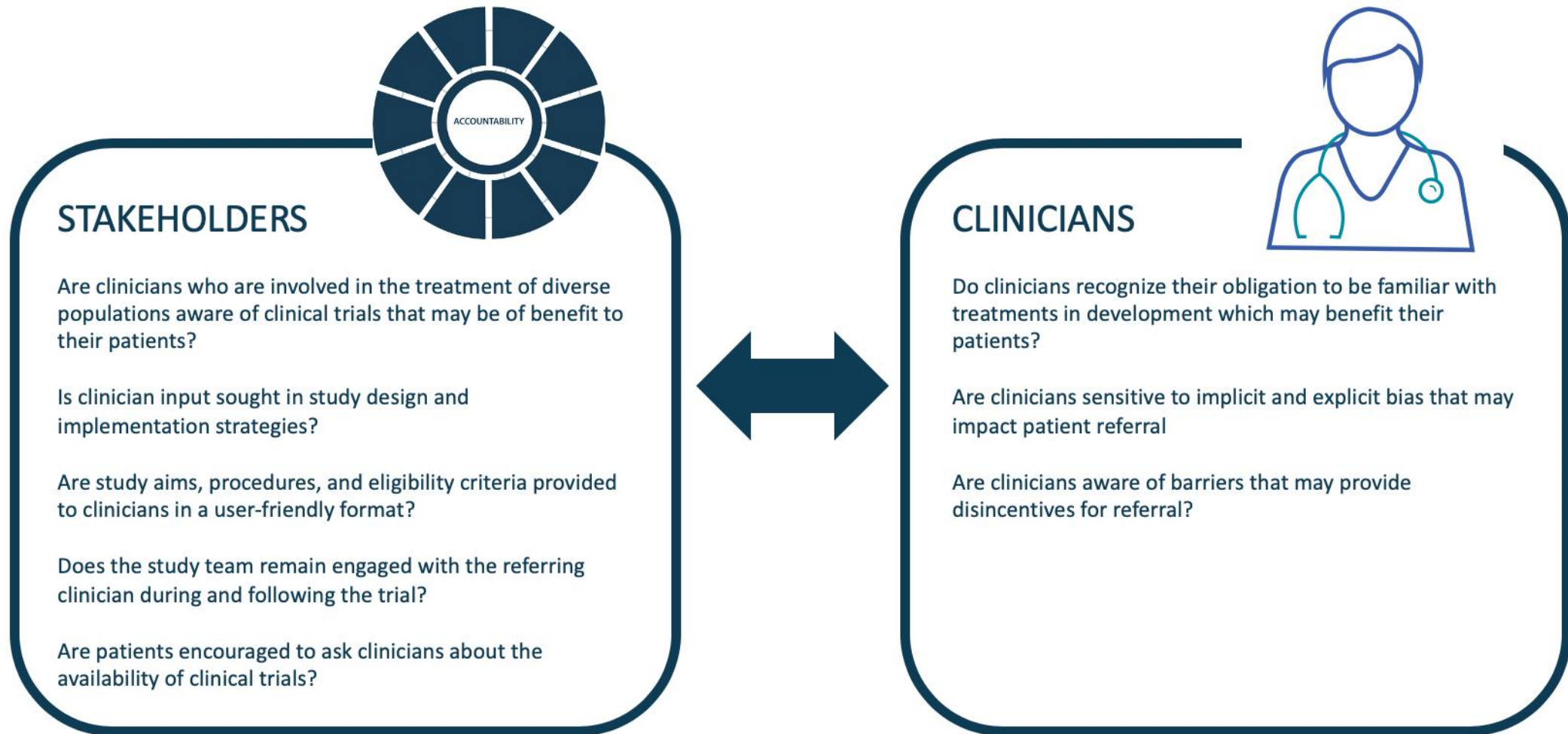
Funding Agencies



Patients/Participants



# The role of the clinician



# The Role of the IRB

- Ensure research is ethical, subject selection is fair, benefit is optimized benefit
- Create expectations, promoting dialogue with investigators and sponsors
- Establish accountability
- Foster competence, education, and the development of infrastructure



# The Role of the Journal

- Require the submission for review of demographic characteristics on the enrolled clinical trial sample and method of ascertainment
- Require comment from authors regarding the generalizability of the research findings as they relate to underserved or underrepresented groups
- Be objective, impartial, and inclusive when selecting and editing publications
- Diversify and train editors, editorial boards, and journal staff



# Today's speaker



## Fabian Sandoval, M.D

CEO & Research Director at Emerson Clinical Research Institute, Inc.  
Leadership Council Member Society for Clinical Research Sites  
Emmy Winning Host [\*"Tu Salud Tu Familia"\*](#) and Medical Contributor  
Telemundo Washington D.C

## EDHF

Emerson Diversity Health Foundation  
Established 2018



**COMMUNITY  
OUTREACH AND  
EDUCATION**

PATIENTS



**1250**  
PER WEEK



## ECRI

Emerson Clinical Research Institute  
Established 2014



**H.Q. OFFICE  
WASHINGTON D.C.  
PARTNER CLINIC  
(FQHC)**

PATIENTS ON DATABASE



**60K**



## ECC

Emerson Community Clinic  
Established 2018



**LOW COST PRIMARY  
CARE SERVICE**

PATIENTS ON DATABASE



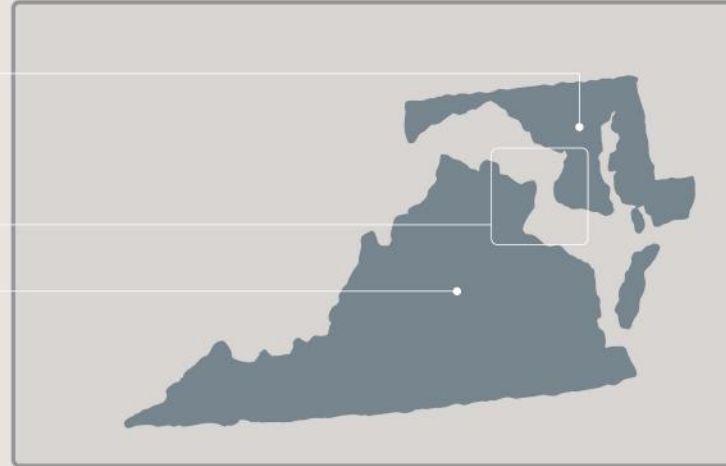
**5K**





¿WHERE DO PATIENTS  
COME FROM?

VA DC MD



**We open**  
Monday – Saturday  
(w/appointment on Sunday)



**No cost**  
transportation for  
research patients



**Migratory  
status or  
health  
insurance**  
**NOT AN  
ISSUE**

# EDHF

Emerson Diversity  
Health Foundation



## TV SHOW



## FREE HEALTH SCREENINGS

- RETINAL IMAGING
- DIABETES
- HYPERTENSION
- CHOLESTEROL
- URINE ANALYSIS
- GLAUCOMA

**60 K**  
VIEWERS  
EVERY  
SATURDAY  
MORNING

**1.8 K** f  
FOLLOWERS  
**9 K** t  
VIEWS YT

**30**  
HEALTH  
FAIRS  
PER  
YEAR

## CONSULATES

- EL SALVADOR
- GUATEMALA
- MEXICO

**Virginia**  
**Falls Church, VA**  
Ophthalmology  
Anterior Chamber  
Posterior Chamber

**New Jersey**  
**Passaic, NJ**  
(FQHC)

**Washington D.C.**  
(FQHC)

## ECRI

Emerson Clinical  
Research Institute



PARTNER CLINICS



**ECC**  
Emerson  
Community Clinic



LABORATORIES

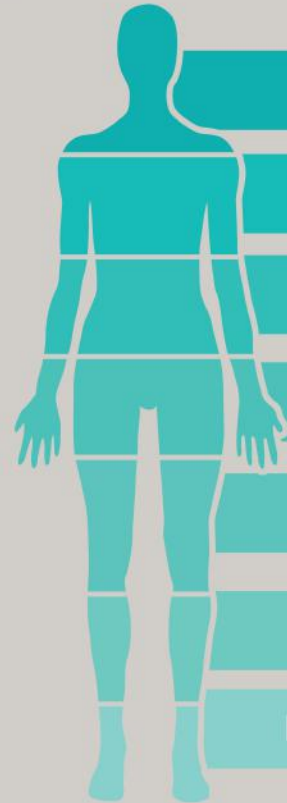
PHYSICAL EXAMS

VACCINES

FAMILY HEALTH

TREATMENTS

PATIENTS



> 7 years old

ID & Immunology

Ophthalmology

Primary care

Men's Health

Women's Health

Metabolic disease

THERAPEUTIC AREAS  
ECRI - ECC



# Today's speaker



## **Chris Reddick, M.D**

Vice President, Head of R&D Health Equity  
Center for Health Equity & Patient Affairs  
Takeda Pharmaceuticals Company Limited

# Strengthening clinical research capacity in underserved communities through Knowledge Sharing programs



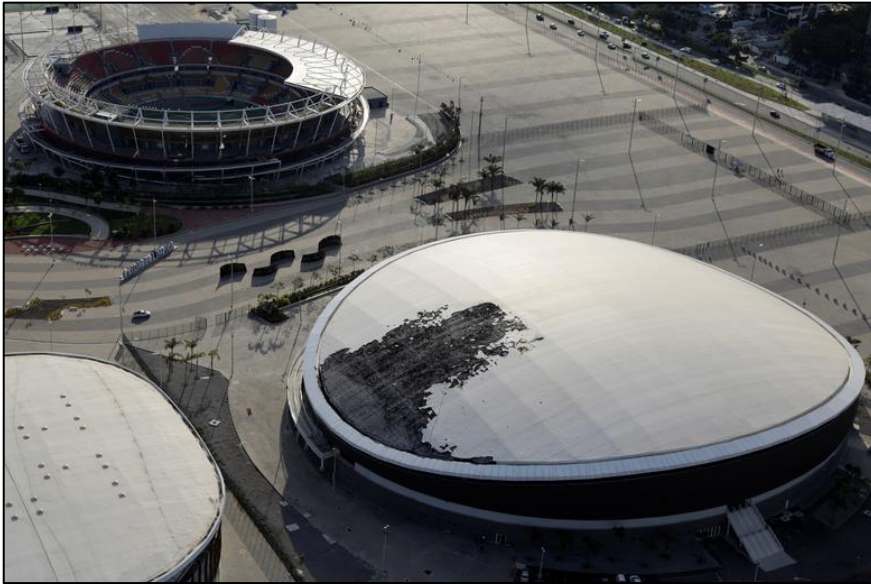
Dr. Chris Reddick  
Vice President, R&D Center for Health Equity  
Takeda Pharmaceuticals

BWH MRCT Learning in: Stakeholder Roles  
January 28, 2021

This will be great for our community, right?

## **After The Flame**

The 2016 Summer Games were supposed to bring Rio and Brazil to new financial and athletic heights. What's left behind? A city and country shrouded by corruption, debt and broken promises.



*The Olympics and other major sporting events usually increase inequality in the host city*

*- BBC News*



# Can clinical trials help strengthen communities long term?

## Social Determinants of Health

<b>Economic Stability</b>	<b>Neighborhood and Physical Environment</b>	<b>Education</b>	<b>Food</b>	<b>Community and Social Context</b>	<b>Health Care System</b>
Employment	Housing	Literacy	Hunger	Social integration	Health coverage
Income	Transportation	Language	Access to healthy options	Support systems	Provider availability
Expenses	Safety	Early childhood education		Community engagement	Provider linguistic and cultural competency
Debt	Parks	Vocational training		Discrimination	Quality of care
Medical bills	Playgrounds	Higher education		Stress	
Support	Walkability				
	Zip code / geography				

### Health Outcomes

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

# Framework for Research Capacity Building Collaborations



Join us:



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# Discussion and Questions