Practical Approaches to Improving Diversity in Clinical Trials

Wednesdays
11AM - 12noon ET
The views and findings expressed in this discussion today and in the guidance are those of the speakers and authors and do not imply endorsement or reflect the views or policies of the U.S. Food and Drug Administration or the affiliated organization or entity of any member who contributed to this work. Individuals have served in their individual capacity.

The MRCT Center is supported by voluntary contributions (www.MRCTCenter.org) and grants.
Practical Approaches to Improving Diversity in Clinical Trials

Wednesdays
11AM – 12noon ET

Recording available Community Awareness, Access, Knowledge
Recording available Workforce Development
Recording available Study Design, Eligibility, Site Selection & Feasibility
Recording available Study Conduct (Recruitment, Retention)
Recording available Data Standards and Analysis
January 27, 2021 Stakeholder Roles and Responsibilities
February 10, 2021 Role of Data in Diversity: Genetics & Real World Data
Today’s topic

Stakeholder Roles and Responsibilities
January 27, 2021
11AM –12noon ET

RADM Richardae Araojio
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

LEARNING IN: A WEBINAR SERIES
Practical Approaches to Improving Diversity in Clinical Trials

mrctcenter.org/diversity-in-clinical-trials
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
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.
Adjusted for age, race and ethnicity widens the gap in mortality compared to Whites

<table>
<thead>
<tr>
<th>Race</th>
<th>Fold Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>PACIFIC ISLANDER</td>
<td>2.5</td>
</tr>
<tr>
<td>LATINO</td>
<td>2.5</td>
</tr>
<tr>
<td>BLACK</td>
<td>2.3</td>
</tr>
<tr>
<td>INDIGENOUS</td>
<td>2.2</td>
</tr>
<tr>
<td>WHITE</td>
<td>1</td>
</tr>
<tr>
<td>ASIAN</td>
<td>0.9</td>
</tr>
</tbody>
</table>

But remain underrepresented in research

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., Joeanna S. Chastain, Pharm.D., and Henry N. Young, Ph.D.

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

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

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

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.

Achieving Diversity, Inclusion, Equity In Clinical Research

Barbara E. Bierer, MD
Sarah A. White, MPH
Laura G. Meloney, MPH, MS
Hayat R. Ahmed, MD
David H. Strauss, MD
Luther T. Clark, MD
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
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.
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
The role of the clinician

STAKEHOLDERS

- Are clinicians who are involved in the treatment of diverse populations aware of clinical trials that may be of benefit to their patients?
- Is clinician input sought in study design and implementation strategies?
- Are study aims, procedures, and eligibility criteria provided to clinicians in a user-friendly format?
- Does the study team remain engaged with the referring clinician during and following the trial?
- Are patients encouraged to ask clinicians about the availability of clinical trials?

CLINICIANS

- Do clinicians recognize their obligation to be familiar with treatments in development which may benefit their patients?
- Are clinicians sensitive to implicit and explicit bias that may impact patient referral?
- Are clinicians aware of barriers that may provide disincentives for referral?
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

ECRI
Emerson Clinical Research Institute
Established 2014

H.Q. OFFICE WASHINGTON D.C.
PARTNER CLINIC (FGHC)

ECC
Emerson Community Clinic
Established 2018

LOW COST PRIMARY CARE SERVICE

PATIENTS

1250 PER WEEK

PATIENTS ON DATABASE

60K

PATIENTS ON DATABASE

5K
WHERE DO PATIENTS COME FROM?

VA  DC  MD

MAP OF AREA

WE OPEN
Monday – Saturday
(appointment on Sunday)

NO COST
transportation for research patients

MIGRATORY
status or health insurance

NOT AN ISSUE
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 Leaning 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

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

Health Outcomes
Mortality, Morbidity, Life Expectancy, Health Care Expenditures, Health Status, Functional Limitations
Framework for Research Capacity Building Collaborations

- Patients, Caregivers and Communities
- Govt. & Public Health Organizations
- Non-Governmental Organizations (NGOs)
- Healthcare Industry
- Academic Institutions
- Local Health Research and Care Delivery Centers
Practical Approaches to Improving Diversity in Clinical Trials

Wednesdays
11AM – 12noon ET

LEANING IN: A WEBINAR SERIES

Recording available  Community Awareness, Access, Knowledge
Recording available  Workforce Development
Recording available  Study Design, Eligibility, Site Selection & Feasibility
Recording available  Study Conduct (Recruitment, Retention)
Recording available  Data Standards and Analysis
January 27, 2021  Stakeholder Roles and Responsibilities
February 10, 2021  Role of Data in Diversity: Genetics & Real World Data
Discussion and Questions