Achieving Diversity, Inclusion, Equity In Clinical Research…and Care

Barbara E. Bierer, MD
Professor of Medicine, Harvard Medical School
Faculty Director, Multi-Regional Clinical Trials (MRTC) Center of BWH & Harvard
Director, Regulatory Foundations, Law & Ethics Program Harvard Catalyst
bbierer@bwh.harvard.edu
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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.
• Clinical trials are needed to develop new treatments and new vaccines.

• Participants in trials should reflect the population affected by the disease, or those intended to utilize the intervention.

• We should not assume that all individuals respond similarly to interventions.

• Underrepresentation in clinical trials of Black, Latinx, Asian, Native American, and other underserved populations—as well as women and individuals at either end of the age spectrum—is not new, and persists in both industry and academic trials, and across therapeutic areas.

• Race and ethnicity are not a biological determinants, but social determinants of health have real biology.

• Diverse representation is not simply a matter of biology, but a matter of health equity, fairness, and public trust.
Health disparities by race in the COVID-19 pandemic

The New York Times
July 5, 2020

Coronavirus cases per 10,000 people

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Centers for Disease Control and Prevention, through May 28

Underrepresentation in COVID-19 clinical trials

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

STATT
Covid-19 clinical trials are failing to enroll diverse populations, despite awareness efforts

Researchers call out lack of diversity in COVID-19 clinical trials

COVID-19 disparities: An urgent call for race reporting and representation in clinical research
Hala T. Borno a, Sylvia Zhang b, Scarlett Gomez b

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

2015-2016

Cardiovascular Disease
N = 92,329

- Black/African: 2.50% (1,415)
- Other race: 97.50% (55,118)

Oncology
N = 7,691

- Black/African: 2.74% (211)
- Other race: 97.26% (7,480)

Psychiatry
N = 5,810

- Black/African: 24.18% (1,405)
- Other race: 75.82% (4,405)

https://www.fda.gov/media/106725/download

23 September 2020
MassCPR
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In the end, an individual is treated
It starts with evidence, information, and trust

• Data must include those populations affected.
• It starts with public and community engagement.
• Clinical trials should:
  o address questions of importance to the community
  o be designed with study outcomes that people care about
  o use language and words that people understand
  o be conducted in ways that decrease burden for the participants, and
  o communicate results to the communities affected
• We should hold each other accountable at every stage.
Leadership:
• Academia
• Industry
• FDA

Multi-stakeholder workgroup, representing:
• Patients Patient Advocates
• Academia
• Pharmaceutical companies
• Non-profit organizations
• Trade associations
• Government agencies
• Research institutes

Each serving in their individual capacity.
Diversity exists across many dimensions

A broad definition of diversity

Dimensions of diversity are not independent variables
Patient and community engagement support diverse participation

- **Forming Relationships**: The patient and community to be in key leadership roles, as advisors, and as consultants.

- **Training and Support**: Patient perspective to influence research priorities and questions

- **Shared Goals**: Seek input to tailor study design and conduct to improve access, enrollment, and retention

- **Sustained partnerships**: Build Trust

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Barriers and Opportunities: Every stakeholder has responsibility

**Sponsors/Institutions/Sites/Regulators**
- Lack of engagement
- Lack of diverse workforce
- Trial time and cost
- Variable regulatory expectations

**Data Collection/Data Analysis**
- Lack of data standards
- Data collection and reporting variable
- Analyses inconsistent

**Investigators/Referring Physicians/Staff**
- Uncertainty regarding scientific utility of inclusion
- Eligibility criteria limiting
- Site feasibility inaccurate
- Inadequate staffing and time constraints
- Recruitment and retention challenges
- Lack of cultural competence and diverse staff

**Patients/Advocates/Communities**
- Lack of awareness
- Lack of access
- Study design and research procedures burdensome
- Outcomes of uncertain value
- Logistics of trial conduct challenging
- Payment and other concerns
- Mistrust
Clear communication is a shared responsibility

- It is not that the listener has “poor literacy.”
- The communicator is responsible for sharing information that is understandable to the listener.
- The listener should be comfortable communicating any lack of understanding

- Plain language
- Numeracy
- Visualization
- Clear design
- Cultural considerations
- Interactive techniques
- Teach-back

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COVID-19 Research Flyers

"Should I join?"

Resources for the public

https://mrctcenter.org/blog/resources/covid-19-clinical-research-flyers/

En Español

¿Debería unirse?

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Participant’s Clinical Trial Journey

**Early Interventions**
- Access
- Recruitment
- Screening
- Awareness

**Study Conduct**
- Informed consent: Participant on study
- On Study visits
- Participant Last visit: End of study treatment
- End of trial LPLV
- Follow-up period

**Data, Data Analysis, and Reporting**
- Data Lock
- Data Analysis Complete
- And Reporting

**Patient and Community Engagement**
- Education & Health Literacy
- Feasibility Assessment
- Eligibility Criteria

**Study Design**
- Informed consent simplification
- Logistical issues
- Decentralized trials
- Payment, transport, childcare, etc.

**Standardized data collection**
- Post-trial access to medicines
- Return of results
- Referring physician engagement

**Data Analysis**
- Results reporting

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Opportunities

- Patient and Community Awareness, Access, Engagement, and Participation
- Eligibility and Study Design
- Logistics and Flexibility
- Data Standards and Analyses
- Innovation
- Genetics
- Diverse representation in databases
- Trust
• Genentech/Roche:
  o Phase 3 trial of patients with COVID-19 associated pneumonia
  o Patients who received tocilizumab (Actemra®) in addition to standard of care were 44% less likely to progress to mechanical ventilation or death.
  o 85% of the 389 patients were from minority racial and ethnic groups, majority Hispanic, significant representation of Black or African American and Native American populations.

It can be done.

https://us11.campaign-archive.com/?u=f8609630ae206654824f897b6&id=5aa95a0553
The work ahead

• What can each of us do now?
  ‣ One step at a time towards change

• Need for local, national, and international focus going forward

• Committing to inclusion is our first step.

“...the real work of change is done year by year, month by month, and day by day, by all of us, by each of us...”

mrctcenter.org/diversity-in-clinical-trials
Discussion and Questions