Achieving Diversity, Inclusion, Equity In Clinical Research

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McKinsey Roundtable
November 5, 2020
Disclaimer

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The MRCT Center is supported by voluntary contributions (www.MRCTCenter.org) and grants.
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.
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- Amgen Inc.
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- Sanofi
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Addressing emerging issues of MRCTs

Recognizing the need to focus on and with the participant

- Post trial access to medicines
- Return of Results, Aggregate and Individual
- Health Literacy
- Diversity, Inclusion, Equity

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

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>Fold Increase</th>
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<td>White</td>
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Adjusted for age, race and ethnicity widens the gap in mortality compared to Whites.

https://www.apmresearchlab.org/covid/deaths-by-race
Health disparities by race and ethnicity in the COVID-19 pandemic

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But are underrepresented in research

Racial Disproportionality in Covid Clinical Trials

Daniel B. Chastain, Pharm.D., Sharmon P. Osae, Pharm.D., Andrés F. Henao-Martinez, 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 Jakuvec, MSJ

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

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

mrctcenter.org/diversity-in-clinical-trials
Drug Trial Snapshots: Summaries

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

- **Cardiovascular Disease**
  - N = 92,329
  - 2.50% (1,415 Black/African, 97.50% Other race)

- **Oncology**
  - N = 7,691
  - 2.74% (211 Black/African, 97.26% Other race)

- **Psychiatry**
  - N = 5,810
  - 24.18% (1,405 Black/African, 75.82% Other race)

For more information, visit [https://www.fda.gov/media/106725/download](https://www.fda.gov/media/106725/download)
• 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 cannot 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; social determinants of health have a real impact on biology.
• Diverse representation in clinical trials is not simply a matter of biology, but a matter of health equity, fairness, and public trust.
Leadership

- 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.
MRCT Diversity Workgroup

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Shari Bodnoff*, Novartis
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Li Chen, Amgen
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Maria De Leon*, Parkinson’s Foundation
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Eldrin Lewis, Brigham and Women’s Hospital, currently Stanford University

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Latha Palaniappan, Stanford University
Claude Petit, Boehringer Ingelheim
Claire Pigula*, Biogen
Melissa Poindexter*, Advances in Health
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Bryant (Abel) Riera*, Population Council
Suzanne M. Rivera, Case Western Reserve University
Frank W. Rockhold, Duke University
Ricardo Rojo*, Pfizer
Rosanne Rotondo*, Novartis
Fabian Sandoval, Emerson Clinical Research Institute
Richard Sax*, IQVIA
Hollie Schmidt, Accelerated Cure Project for Multiple Sclerosis
Karlin Schroeder, Parkinson’s Foundation
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Jessica Scott*, Takeda
Lana Skirboll, Sanofi
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Ann Taylor*, Columbia University
Paul Underwood, Boston Scientific
Junyang Wang, Food and Drug Administration (FDA)
Robert Winn*, University of Illinois
Gerren Wilson*, Genentech/ A Member of the Roche Group
Crispin Woolston, Sanofi
Honghui Zhou*, Johnson & Johnson

*involvement limited in time

5 November 2020
McKinsey Roundtable
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Sections of the Guidance Document

• Preface
• Part A – Building the Case
• Part B – Background, Ethical Principles, Regulatory Directives
• Part C – Broadening Engagement
• Part D – Data Standards and Analysis
• Part E – Study Design, Conduct, and Implementation
• Part F – Stakeholder Commitments and the Future
• Part G – Appendix

Toolkit

• Key Summary
• Recommendations
• Tools
• Case Examples
Diversity exists across many dimensions

A broad definition of diversity

- Race
- Ethnicity
- Sex
- Gender
- Ancestry
- Age
- Social Determinants of Health
- Environmental factors
- Genetics
- Co-morbidities
- Concurrent medications
- Other

Intersectionality:
- Dimensions of diversity are not independent variables
Barriers: 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**
- Uncertain 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
- Payment and other concerns
- Mistrust
Individuals must be invited
Participant’s Clinical Trial Journey

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

**Study Conduct**
- Informed consent: Participant on study
- On study: Additional testing
- Randomization
- On-Study visits
- Follow-up period
- Participant Last visit: End of study treatment
- End of study treatment
- End of trial
- LPLV
- Data Analysis
- Complete
- And Reporting

**End of Study, 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, transportation, childcare, etc.

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

**Data standards**
- Data analysis
- Results reporting
- Community outreach

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5 November 2020
McKinsey Roundtable
Heterogeneity of Treatment Effects in Clinical Trials: Methods and Innovations

NOVEMBER 30, 2020 - DECEMBER 1, 2020
8:30am-1pm ET

Virtual Conference hosted by MRCT Center in collaboration with FDA

Clear communications throughout the product development program

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

Informed Consent
Data Collection
Written Materials
Verbal Communications

In a language understandable to the participant
Opportunities: What can we do?

**Trial Design**
- Characterize target population based on epidemiology, disease burden and demographics
- Engage patient population to maximize recruitment and retention strategies and minimize burden of trial

**Site Selection**
- Determine access to potential target population to guide country, region, and site selection
- Use data-driven strategies
- Determine the feasibility of enrollment figures for target subpopulations in partnership with site(s)

**Site Support & Communication**
- Communicate targets for enrollment including demographic projections
- Assist sites with local recruitment plan and outreach activities
- Assess and support each site's cultural readiness
- Provide diversity training to investigators and site staff

**Accountability**
- Ensure recruitment strategy is informed by patient preferences
- Connect with referral networks in the community, including organizations directly involved with target population
- Monitor and communicate site progress, address and adjust with site as needed
Solve for logistical challenges

- Easy and quick reimbursement processes
- Compensation for time, burden, possibly missed work/caregiver support
- Flexible, extended site hours (after work hours and weekends)
- On-site childcare and eldercare
- Provide transportation or assist with arrangements
- Health literate study information in the language of the participant
- Culturally competent and linguistically-capable staff
- Decentralized and virtual trials
- Digitally-enabled trials
Diversity and inclusion during the product approval process

- CTA review provides an opportunity to develop diversity & inclusion strategies
- Review process may include assessment of diversity & inclusion strategies
- Before the end of Phase 2, regulatory groups and sponsors discuss large-scale studies in Phase 3 and pediatric study plans; D&I strategies and plans can be discussed here
- Post-approval risk assessments may establish how to include diversity & inclusion strategies in post-marketing clinical trials
Key Opportunities & Future Actions

• Patient and Community Awareness, Access, Engagement, and Participation; Trust, Trustworthiness
• Workforce Diversity
• Eligibility and Study Design
• Logistics and Flexibility
• Data Standards and Analyses
• Innovation
• Genetics
• Diversity in data sources and databases; RWE
Accountability in Partnership

Holding ourselves and one another accountable

- Metrics
- Transparency
- Dialogue
The work ahead

• What can each of us do now?

• Targeted recommendations for special populations

• Additional tools and resources

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

“...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
Practical Approaches to Improving Diversity in Clinical Trials

Wednesdays
11AM –12noon ET

Recording available

October 28, 2020  Community Awareness, Access, Knowledge
November 18, 2020  Workforce Development
December 9, 2020  Study Design, Eligibility, Site Selection & Feasibility
January 13, 2021  Study Conduct (Recruitment, Retention)
January 27, 2021  Data Standards and Analysis
February 10, 2021  Stakeholder Roles and Responsibilities
Role of Data in Diversity: Genetics & Real World Data
DEI in Clinical Research Roundtable: in Planning

- Vision
- Coordination of ongoing efforts and initiatives
- Begin with information sharing
- What is missing
- What we can achieve collectively

Steering Committee:
- Alliance
- AAMC
- BIO
- FDA
- NIH
- NHC
- PhRMA

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Discussion and Questions
Thank you

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