MULTI-REGIONAL CLINICAL TRIALS

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

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.

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.

Executive & Steering Committee Members

Executive Committee

- Alexion Pharmaceuticals
- Amgen Inc.
- AstraZeneca
- Bill & Melinda Gates Foundation
- Brigham & Women's Hospital
- Eli Lilly & Company
- GlaxoSmithKline
- Harvard University
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- Comprehensive and Integrative Medicine Institute (CIMI)
- Daegu Catholic University Medical Center
- Deloitte Consulting
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- Indian Society of Clinical Research
- IQVIA
- Kowa Research Institute
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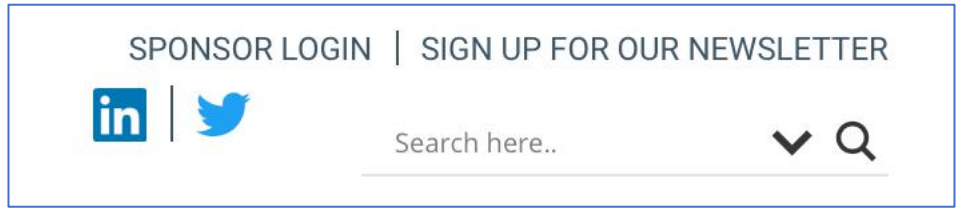
- Pharmaceuticals Inc
- PRAXIS Australia
- PRIM&R
- Roche Genentech
- Sanofi
- Target Health
- Veristat, LLC
- WIRB-Copernicus Group

The MRCT Center's work

Addressing emerging issues of MRCTs



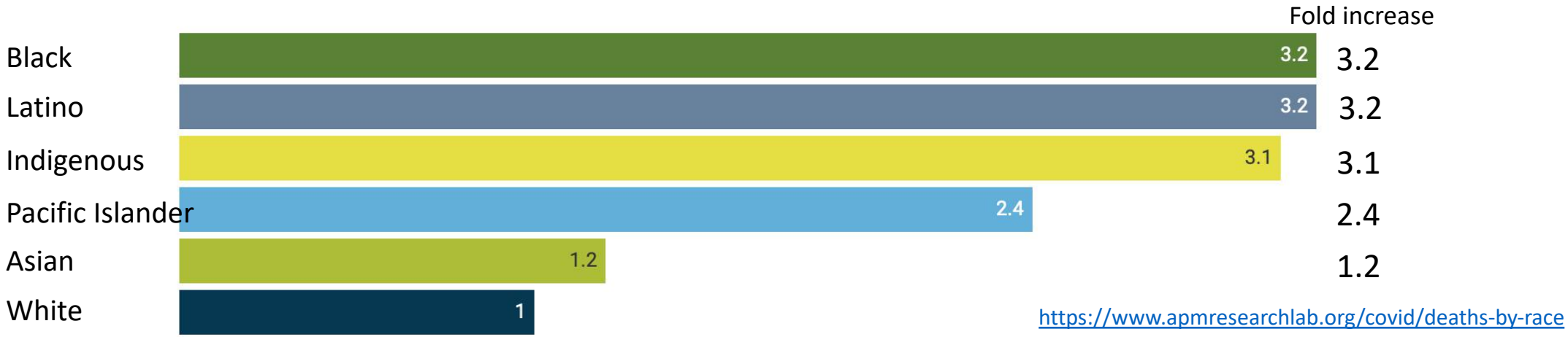
https://mrctcenter.org

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

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

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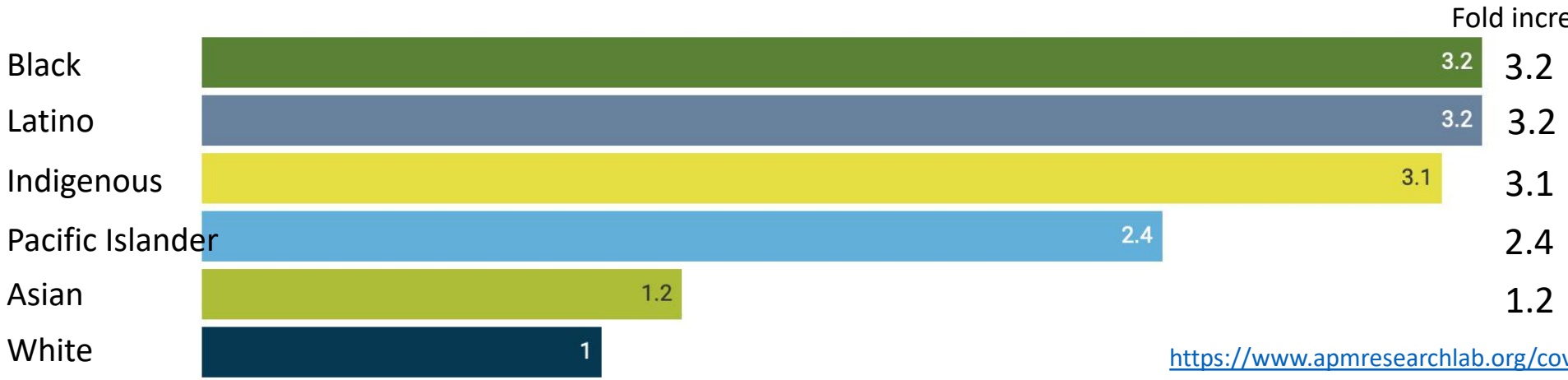


https://www.apmresearchlab.org/covid/deaths-by-race

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

News & Analysis

Medical News & Perspectives

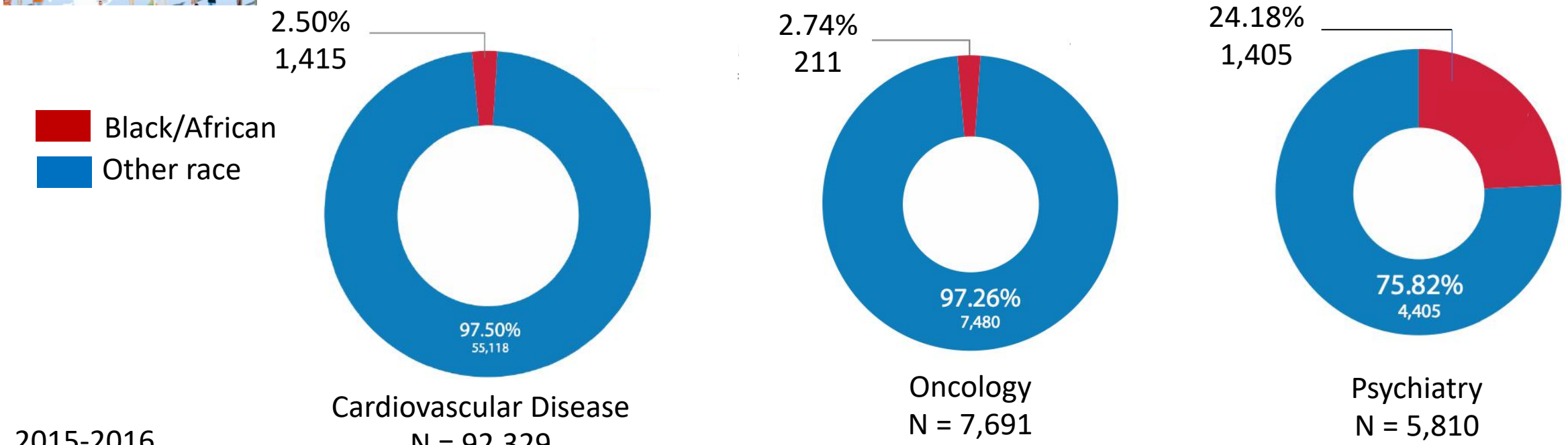
Researchers Strive to Recruit Hard-Hit Minorities Into COVID-19 Vaccine Trials

Mary Chris Jaklevic, MSJ

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

Drug Trial Snapshots: Summaries

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



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

Background

- 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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Stacey Bledsoe* , Eli Lilly and Company
Shari Bodnoff* , Novartis
Racquel Bruton , Biogen
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Li Chen, Amgen
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Maria De Leon*, Parkinson's Foundation
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Rachael Fones, IQVIA
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Melissa Heidelberg, Genentech/ A Member of the Roche Group
Quita Highsmith, Genentech/ A Member of the Roche Group
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Aarthi B. Iyer*, Kinetiq, now Advarra
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Jonathan Jackson*, Massachusetts General Hospital
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*involvement limited in time

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Latha Palaniappan, Stanford University
Claude Petit, Boehringer Ingelheim
Claire Pigula*, Biogen
Melissa Poindexter*, Advances in Health
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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
Mary Scroggins*, Pinkie Hugs
Jessica Scott*, Takeda
Lana Skirboll, Sanofi
Steven Snapinn, Seattle- Quilcene Biostatistics
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Sara Tadesse-Bell, Genentech/ A Member of the Roche Group
Ann Taylor*, Columbia University
Paul Underwood, Boston Scientific
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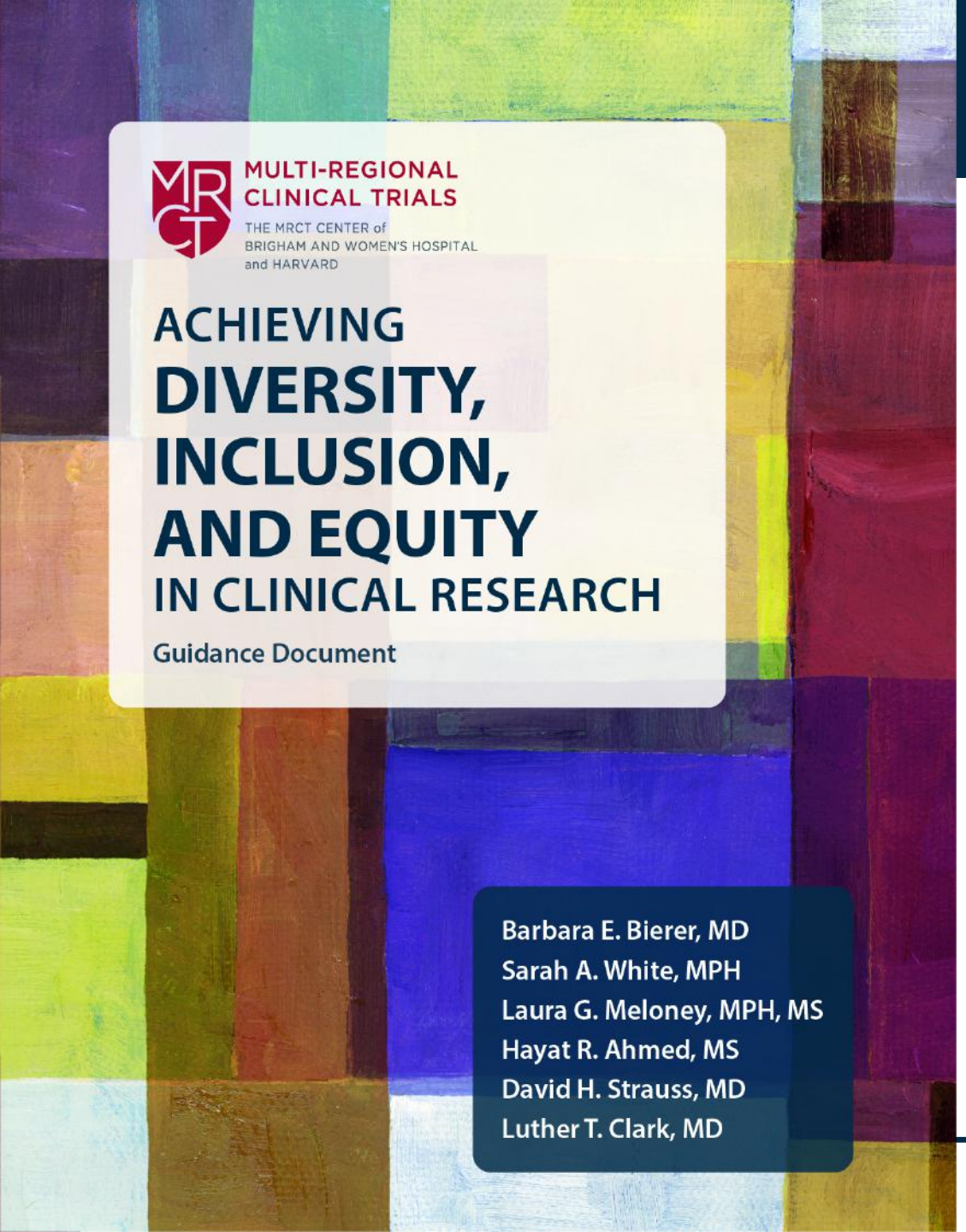
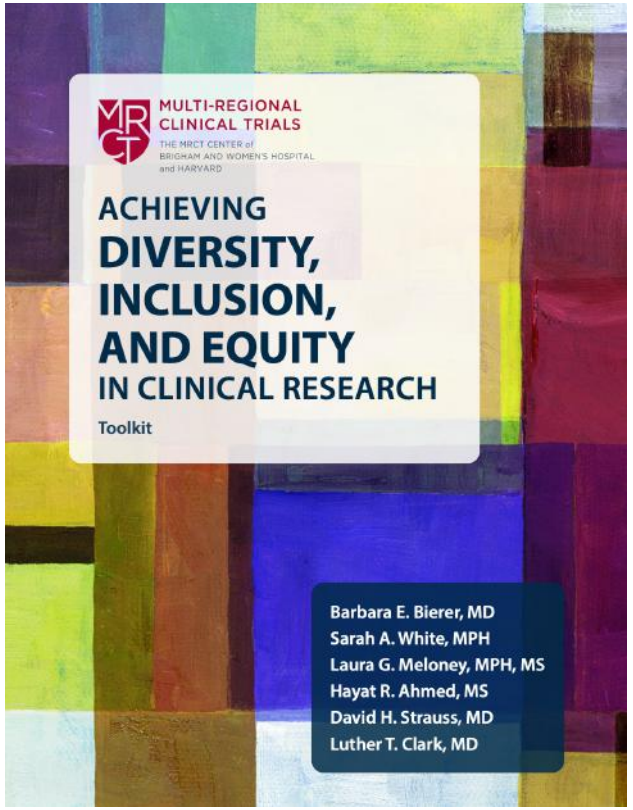
Robert Winn*, University of Illinois
Gerren Wilson*, Genentech/ A Member of the Roche Group
Crispin Woolston, Sanofi
Honghui Zhou*, Johnson & Johnson





Achieving Diversity, Inclusion, Equity In Clinical Research

Guidance and Toolkit

Released 6 August 2020

mrctcenter.org/diversity-in-clinical-trials

Sections of the Guidance Document

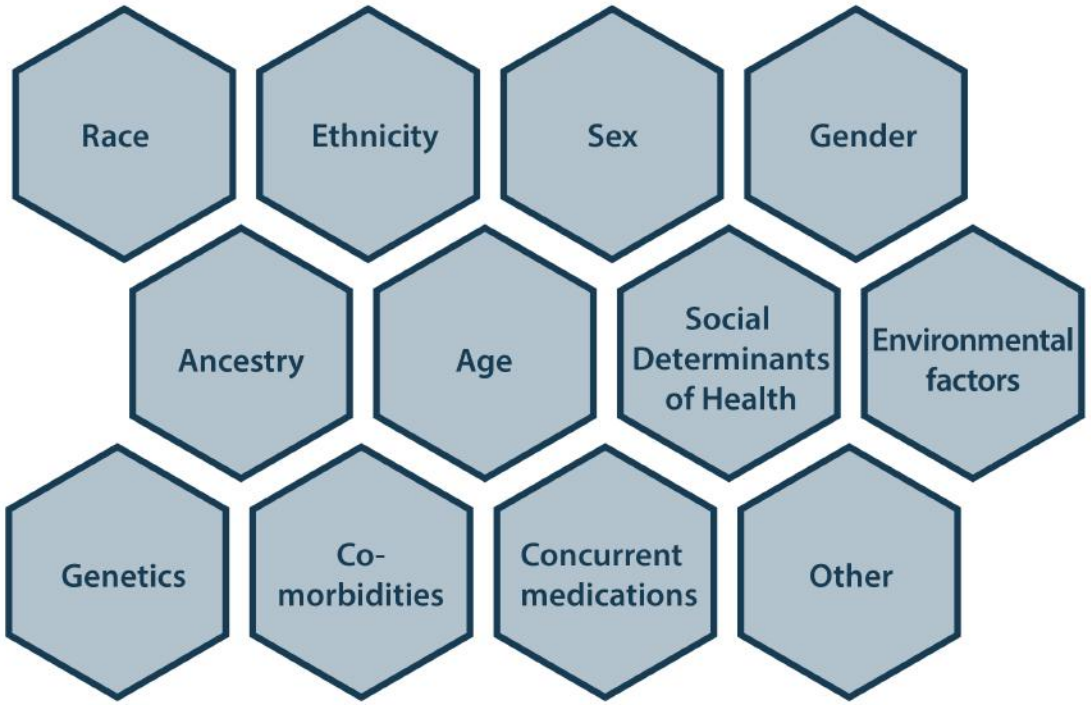
- Preface
- Part A – Building the Case
- Part B – Background, Ethical Principles, Regulatory Directives
- Part C – Broadening Engagement
- Part D – Data Standards and Analysis
- Part E – Study Design, Conduct, and Implementation
- Part F – Stakeholder Commitments and the Future
- Part G – Appendix

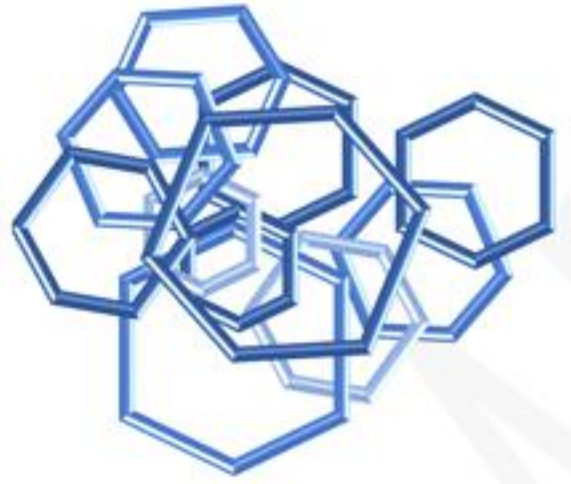
Toolkit

- Key Summary
- Recommendations
- Tools
- Case Examples

Diversity exists across many dimensions

A broad definition of diversity





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

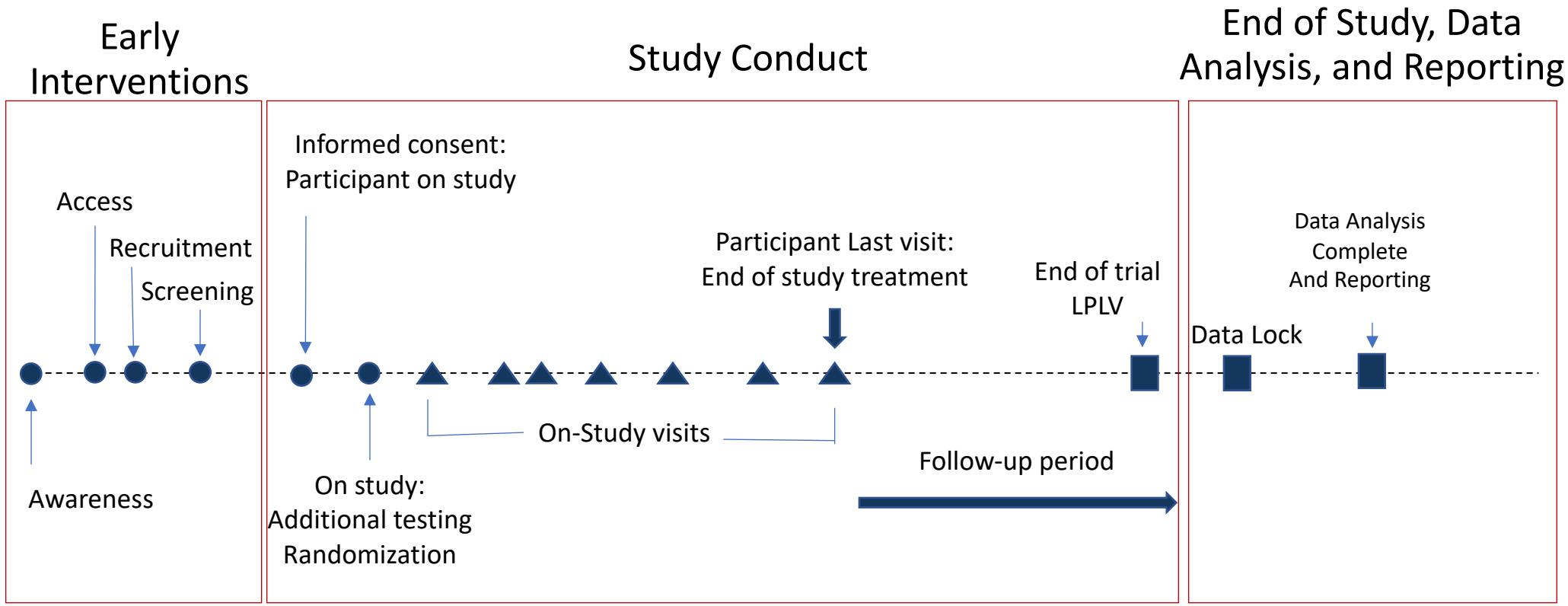
- Uncertain scientific utility of inclusion
- Eligibility criteria limiting
- Site feasibility inaccurate
- Inadequate staffing and time constraints
- Recruitment and retention challenges
- Lack of cultural competence and diverse staff

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



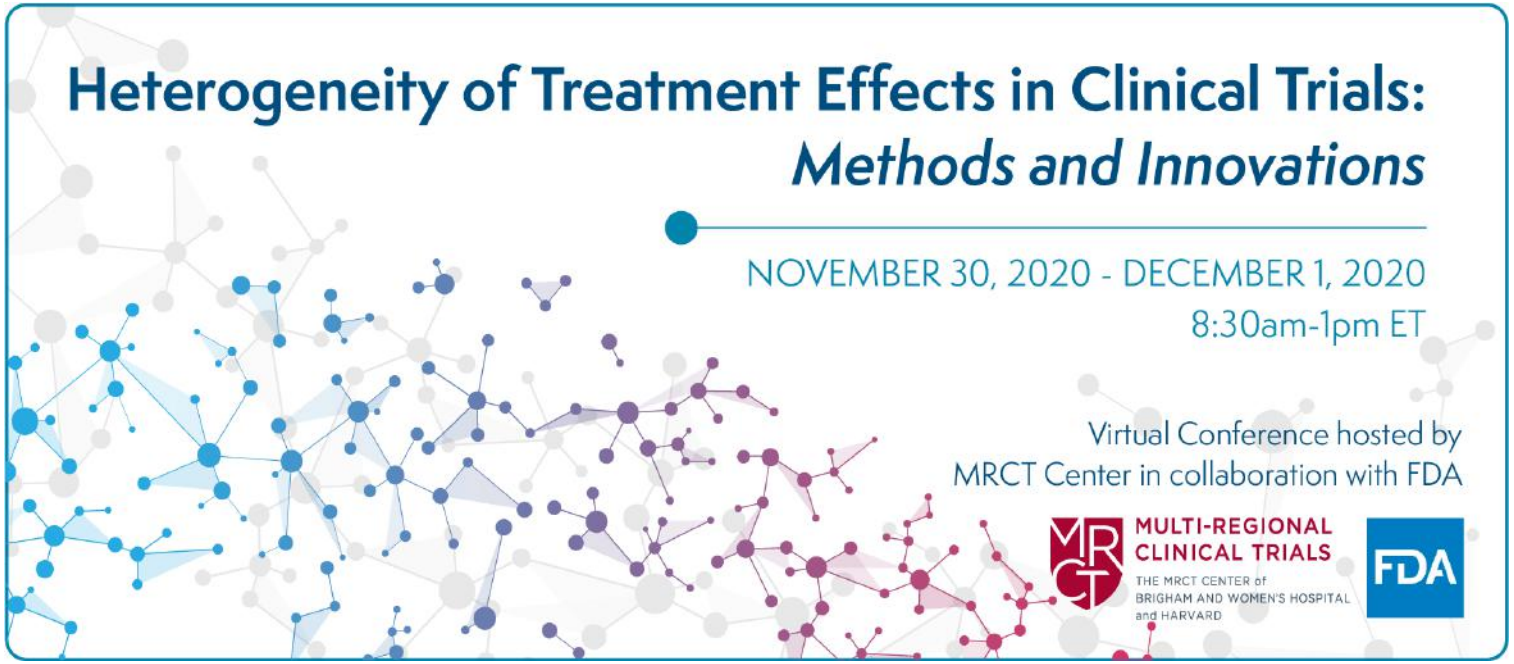
Patient and
Community Engagement
Education & Health Literacy
Feasibility Assessment
Eligibility Criteria

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

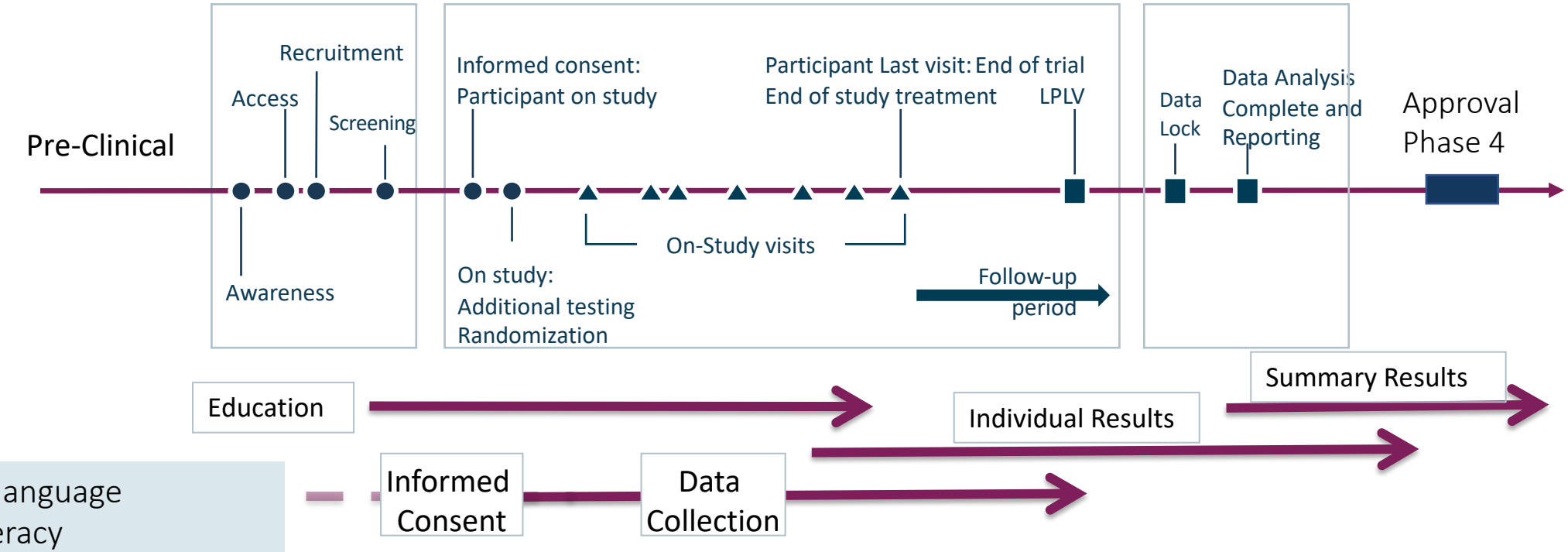
Data standards
Data analysis
Results reporting
Community outreach

FDA and MRCT Center Conference



https://mrctcenter.org/news-events/heterogeneity-of-treatment-effects-in-clinical-trials-methods-and-innovations/

Clear communications throughout the product development program

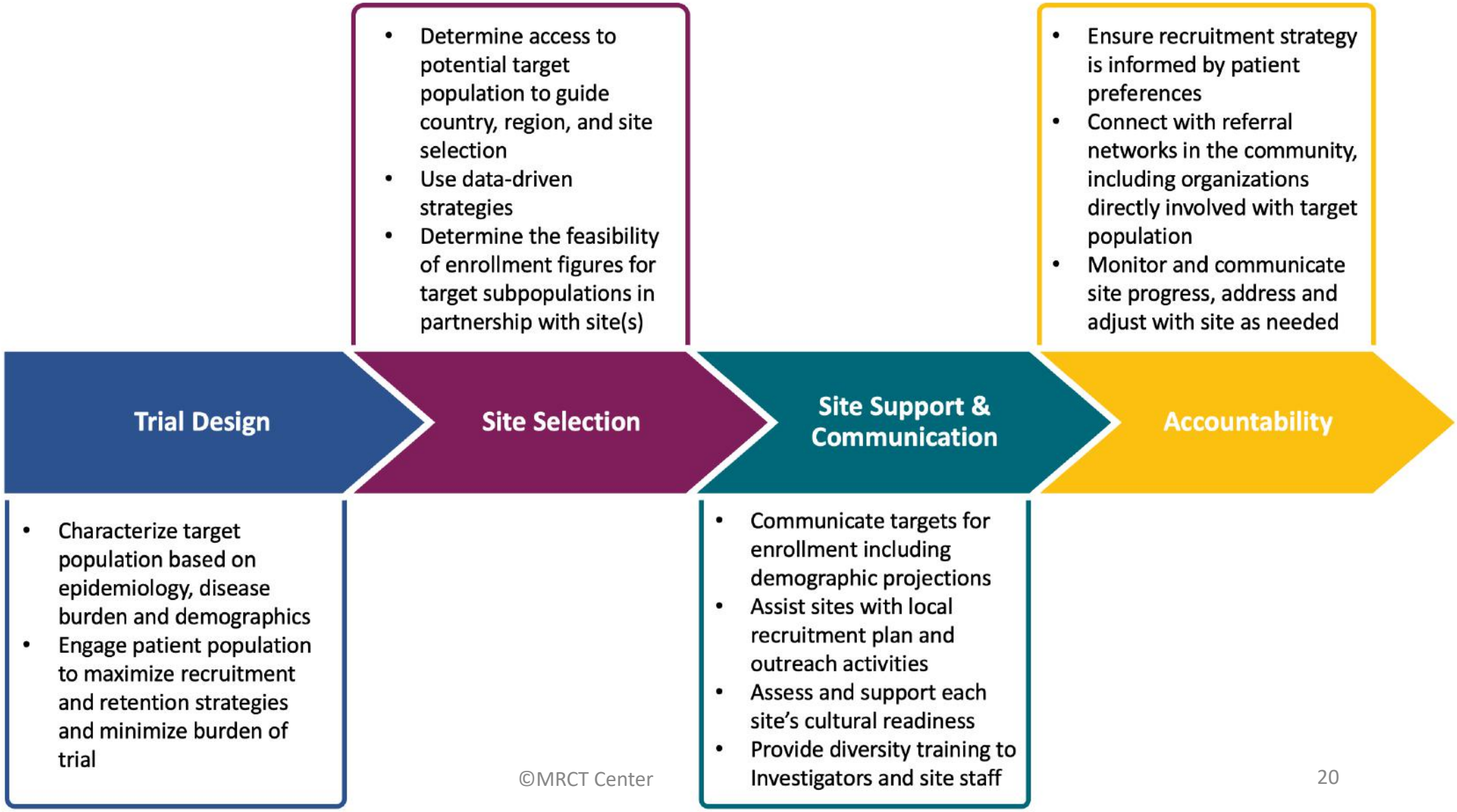


- Plain language
- Numeracy
- Visualization
- Clear design
- Cultural considerations
- Interactive techniques
- Teach-back

Written Materials
Verbal Communications

In a language understandable to the participant

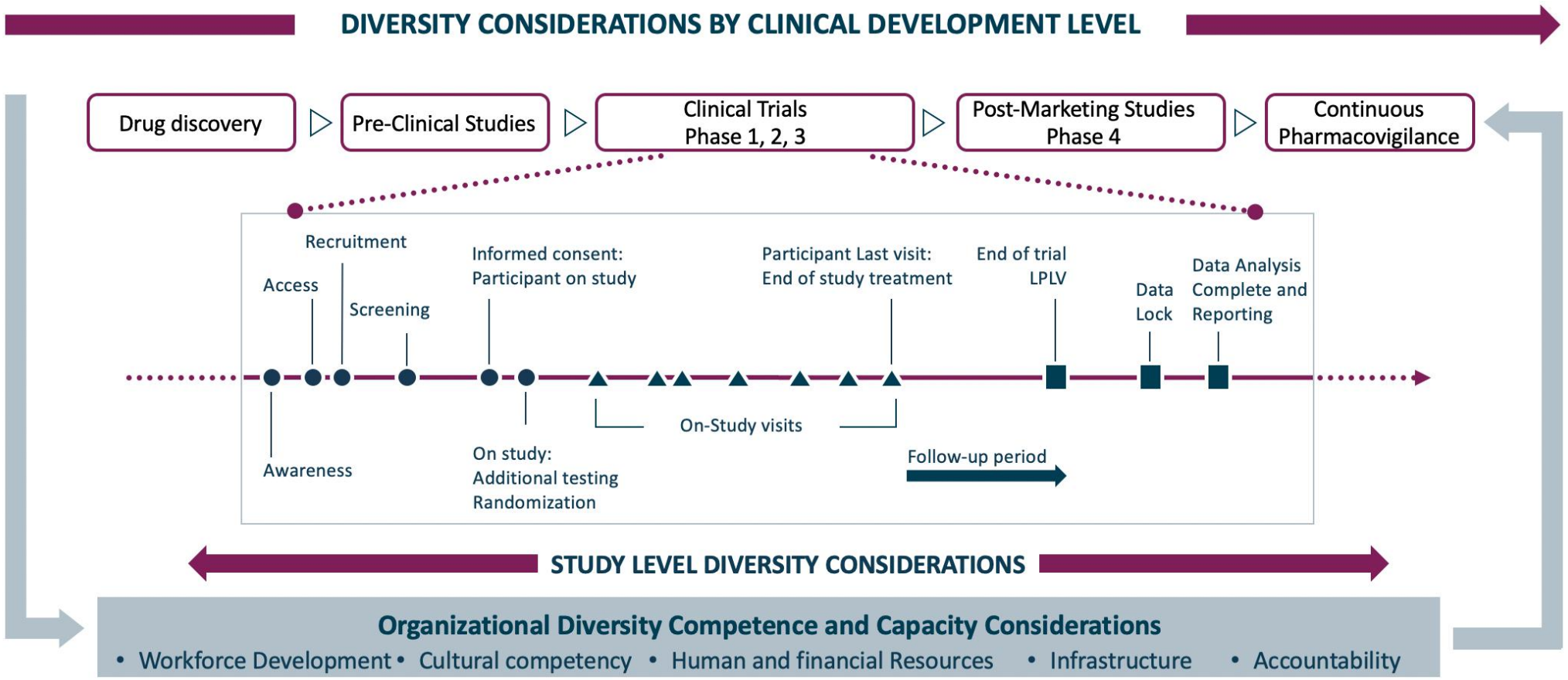
Opportunities: What can we do?



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

Product Development Pathway



Workforce Development

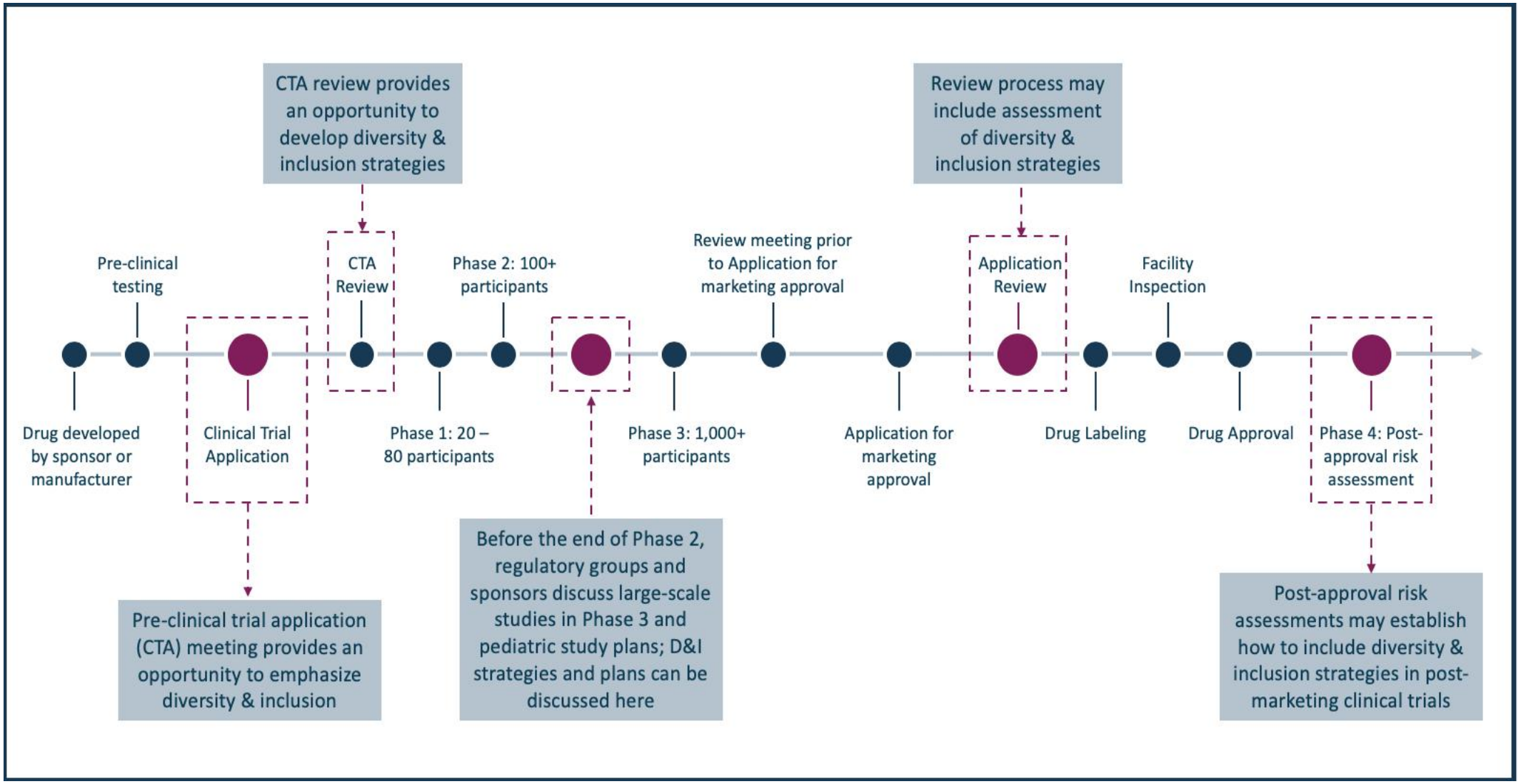
Cultural competency

Resources: human and financial

Infrastructure

Accountability

Diversity and inclusion during the product approval process



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
MULTI-REGIONAL
CLINICAL TRIALS
THE MRCT CENTER of
BRIGHAM AND WOMEN'S HOSPITAL
and HARVARD
LEANING IN: A WEBINAR SERIES
Recording available
Community Awareness, Access, Knowledge
October 28, 2020
Workforce Development
November 18, 2020
Study Design, Eligibility, Site Selection & Feasibility
December 9, 2020
Study Conduct (Recruitment, Retention)
January 13, 2021
Data Standards and Analysis
January 27, 2021
Stakeholder Roles and Responsibilities
February 10, 2021
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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