



**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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# Disclaimer

***The views and findings expressed in this document are those of the 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](http://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.

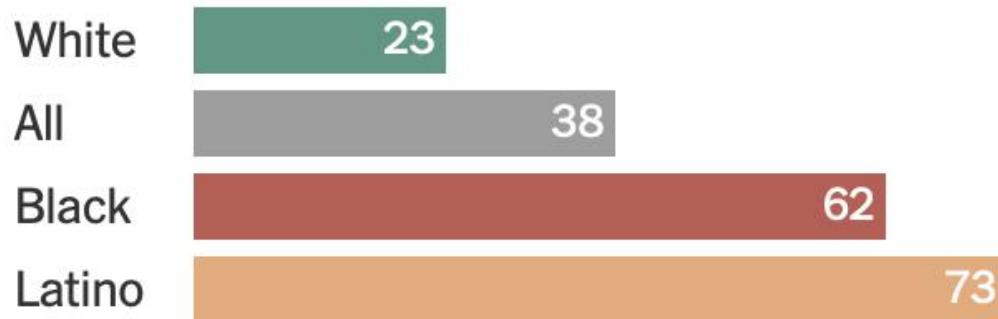
## Our Mission

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



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

## Coronavirus cases per 10,000 people

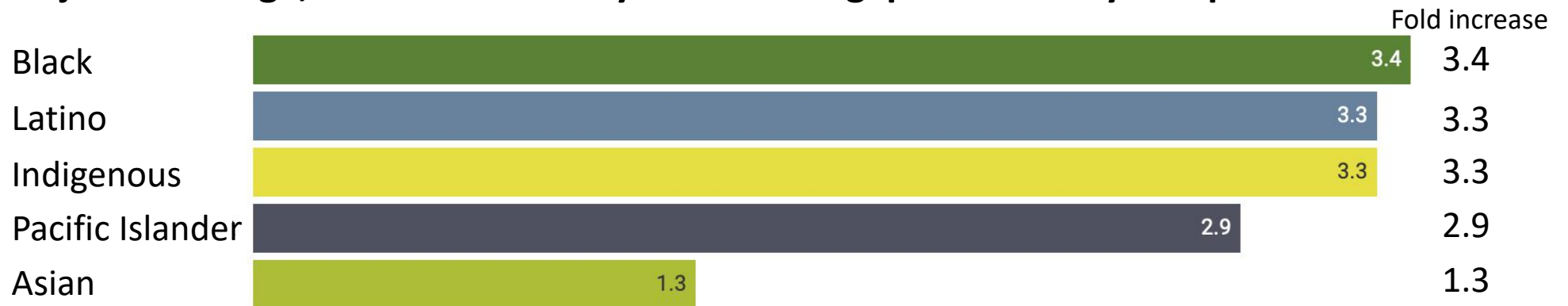


The New York Times

July 5, 2020

<https://www.nytimes.com/interactive/2020/07/05/us/coronavirus-latinos-african-americans-cdc-data.html>

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



APM  
RESEARCH  
LAB

September 15, 2020

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





# COVID-19 clinical trials



The NEW ENGLAND  
JOURNAL of MEDICINE

Perspective  
AUGUST 27, 2020

Contemporary Clinical Trials Communications 19 (2020) 100630



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Contemporary Clinical Trials Communications

journal homepage: <http://www.elsevier.com/locate/conctc>

## 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.

THE READOUT LOUD

STAT

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

By ADAM FEUERSTEIN [@adamfeuerstein](#), DAMIAN GARDE [@damiangarde](#), and REBECCA ROBBINS [@rebeccadrobbins](#)  
/ AUGUST 14, 2020

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

MEDICALNEWS TODAY

## COVID-19 disparities: An urgent call for race reporting and representation in clinical research

Hala T. Borno <sup>a,\*</sup>, Sylvia Zhang <sup>a</sup>, Scarlett Gomez <sup>b</sup>

<sup>a</sup> Department of Medicine, Division of Hematology/Oncology, University of California San Francisco, San Francisco, CA, USA

<sup>b</sup> Department of Epidemiology and Biostatistics, University of California San Francisco, San Francisco, CA, USA

## 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>

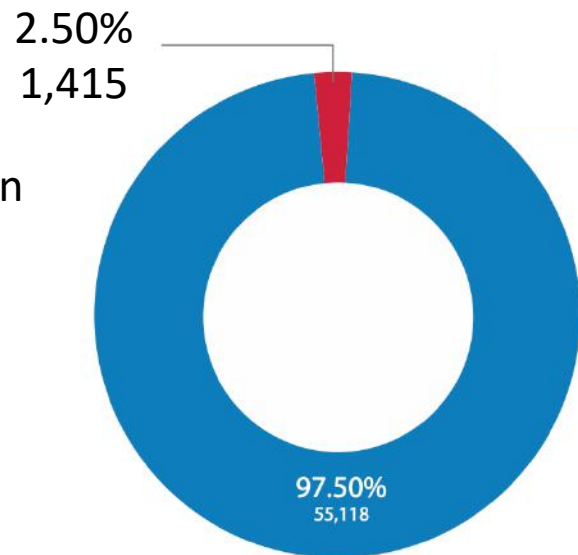


# Drug Trial Snapshots: Summaries

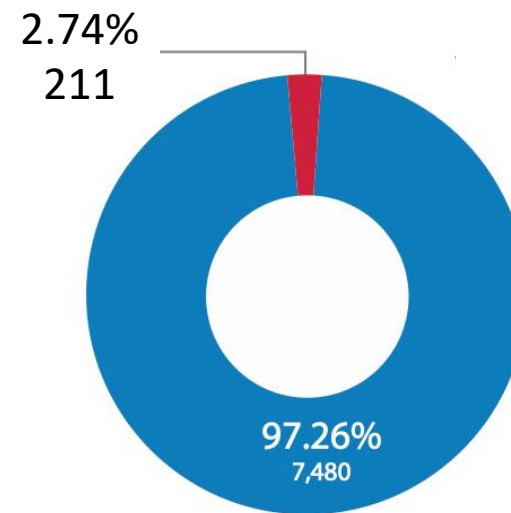


## Participation of Black or African American individuals in clinical trials for oncology, cardiology, and psychiatry

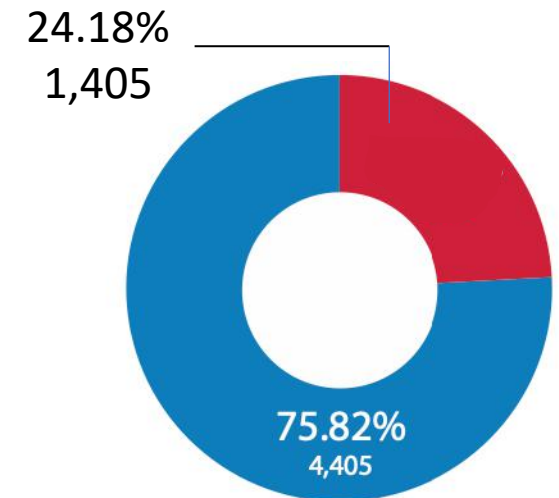
Black/African  
Other race



Cardiovascular Disease  
N = 92,329



Oncology  
N = 7,691



Psychiatry  
N = 5,810

2015-2016

<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 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 a real impact on real 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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Quita Highsmith, Genentech/ A Member of the Roche Group  
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\*involvement limited in time

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Rosanne Rotondo\*, Novartis  
Fabian Sandoval, Emerson Clinical Research Institute  
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Gerren Wilson\*, Genentech/ A Member of the Roche Group  
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Honghui Zhou\*, Johnson & Johnson





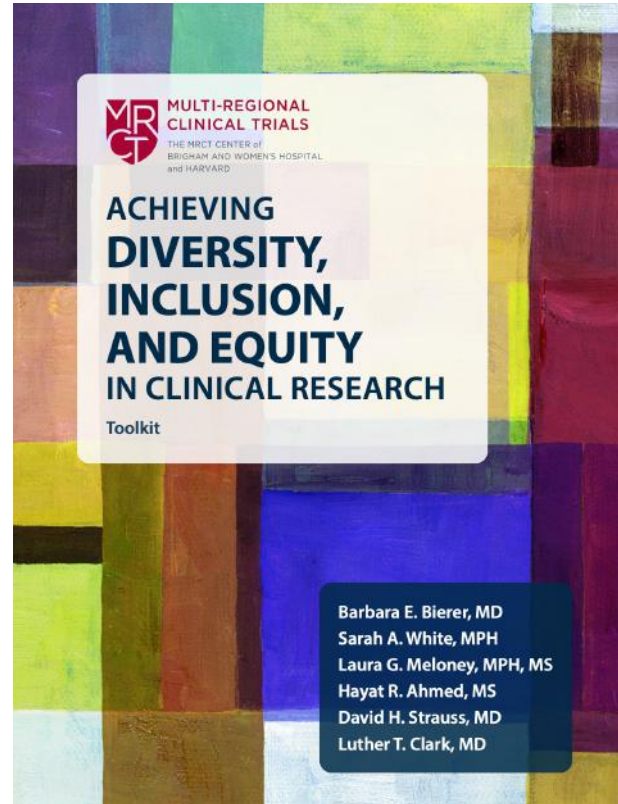
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# ACHIEVING DIVERSITY, INCLUSION, AND EQUITY IN CLINICAL RESEARCH

Guidance Document

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David H. Strauss, MD  
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Achieving Diversity, Inclusion,  
Equity In Clinical Research

Guidance and Toolkit  
Released 6 August 2020

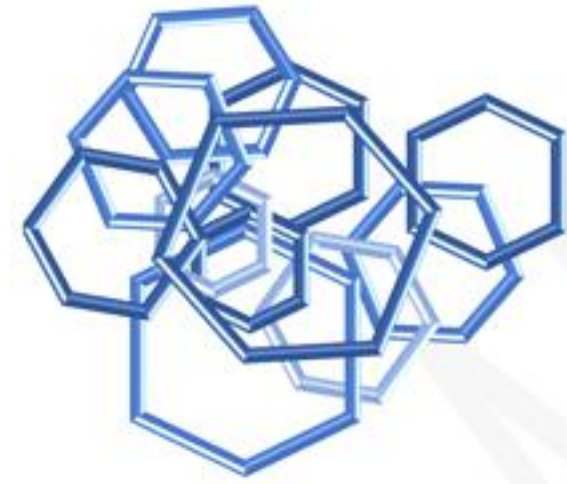
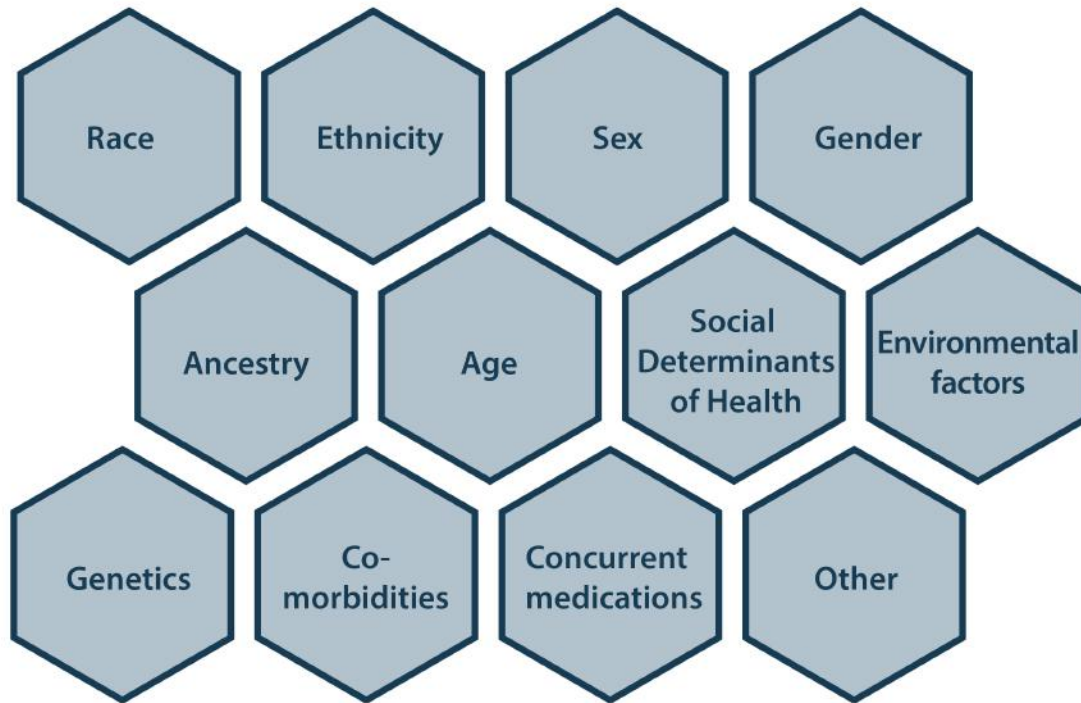
[mrctcenter.org/diversity-in-clinical-trials](https://mrctcenter.org/diversity-in-clinical-trials)





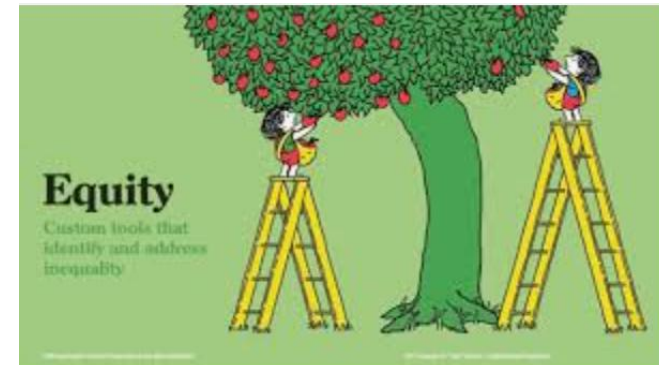
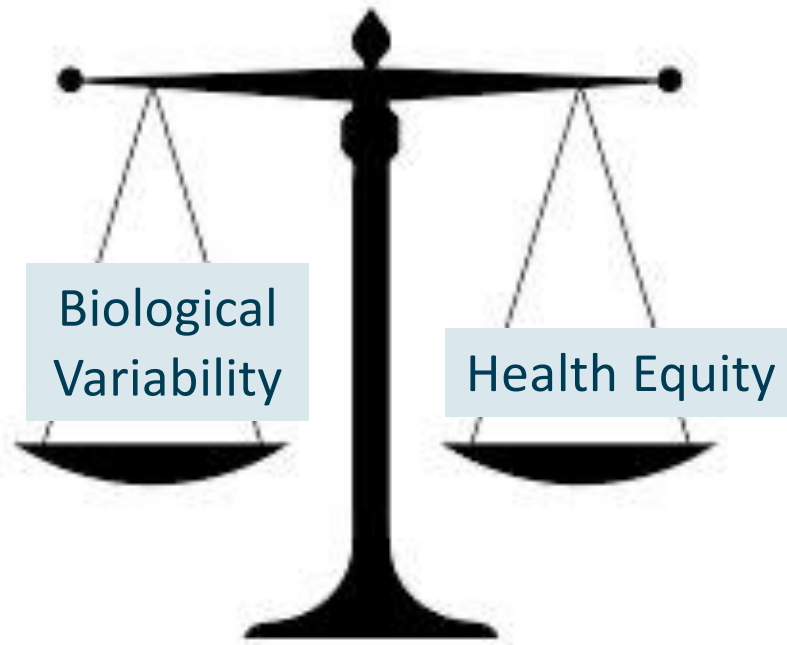
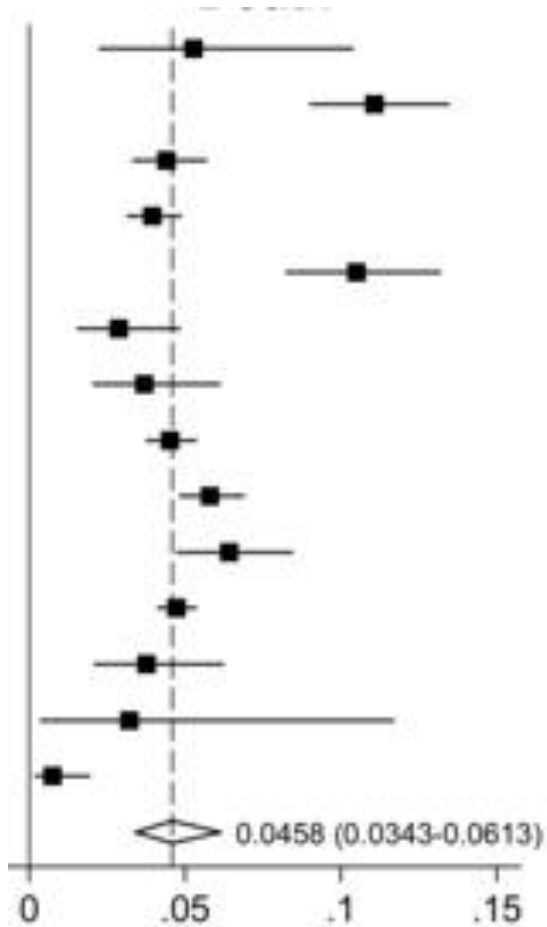
# Diversity exists across many dimensions

## A broad definition of diversity



## Intersectionality:

- Dimensions of diversity are not independent variables



In the end, an individual is being treated



# Sections of the Guidance Document

- Preface
- Part A – Building the Case
- Part B – Background, Ethical Principles, and 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



# Features of the Guidance Document

- Multi-stakeholder contributions and consensus
- Practical and actionable recommendations
- Accountability section considers how each stakeholder can change the paradigm
- Toolkit provides adaptable resources not easily found elsewhere



# 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

# Patient and community engagement support diverse participation

## Forming Relationships

The patient and community to be in key leadership roles, as advisors, and as consultants

## Sustained partnerships

## Training and Support

Patient perspective to influence research priorities and questions

## Shared Goals

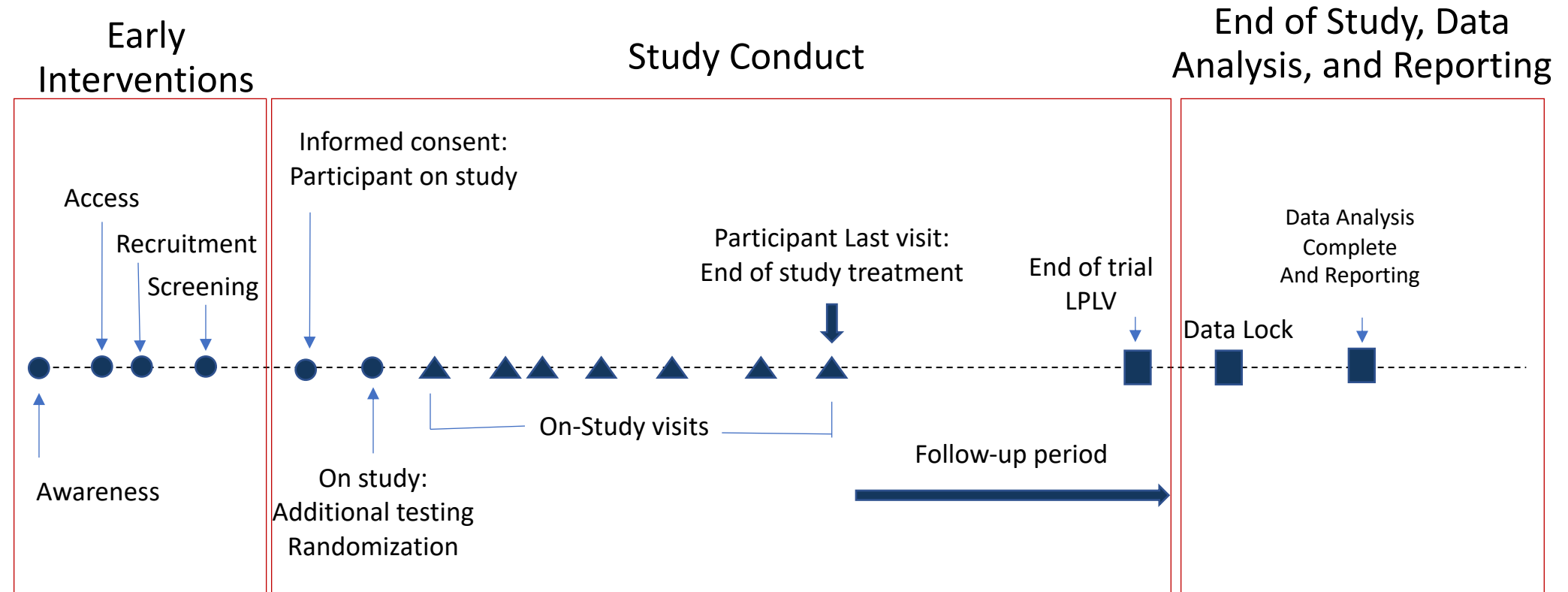
Seek input to tailor study design and conduct to improve access, enrollment, and retention



## Build Trust



# 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.

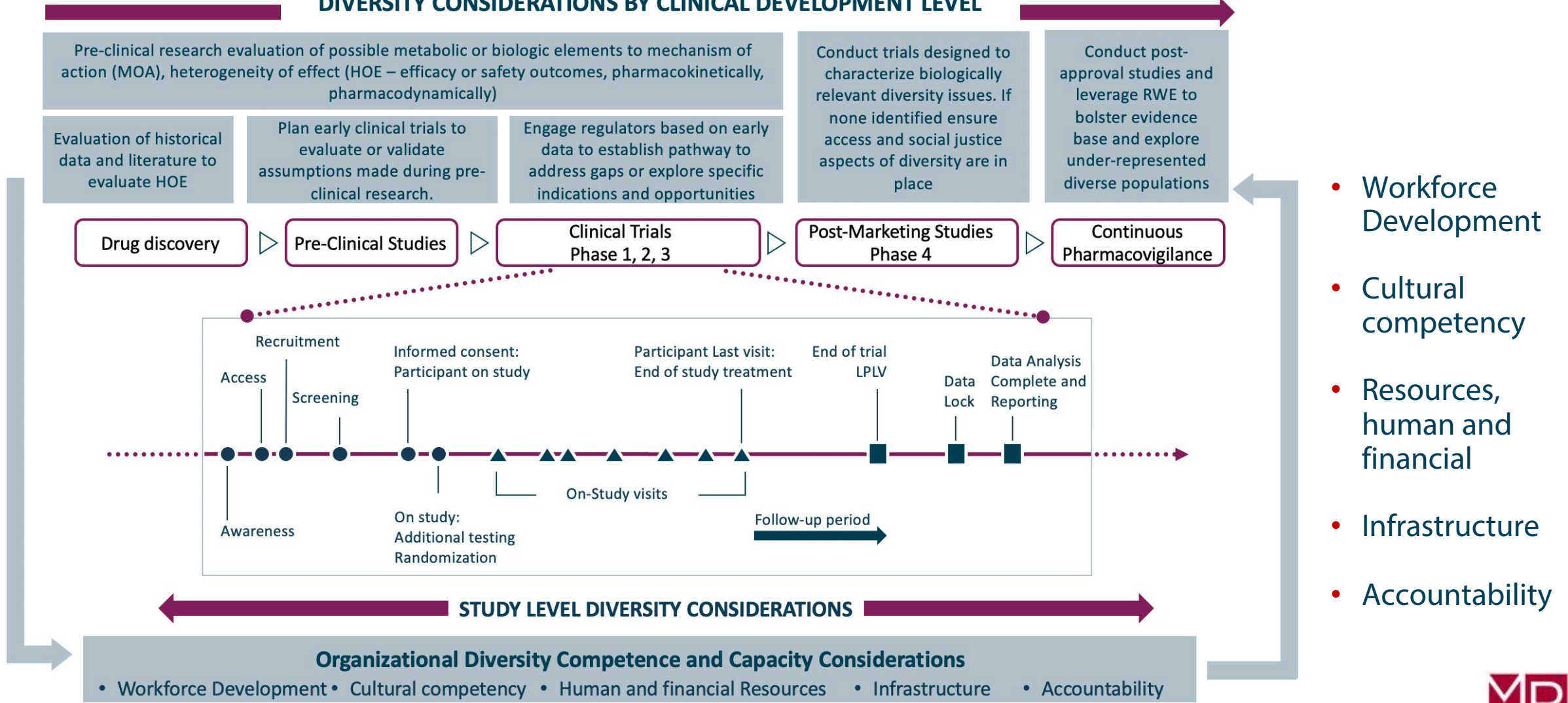
Standardized data collection  
Post-trial access to medicines  
Return of results  
Referring physician engagement

Data standards  
Data analysis  
Results reporting  
Community outreach

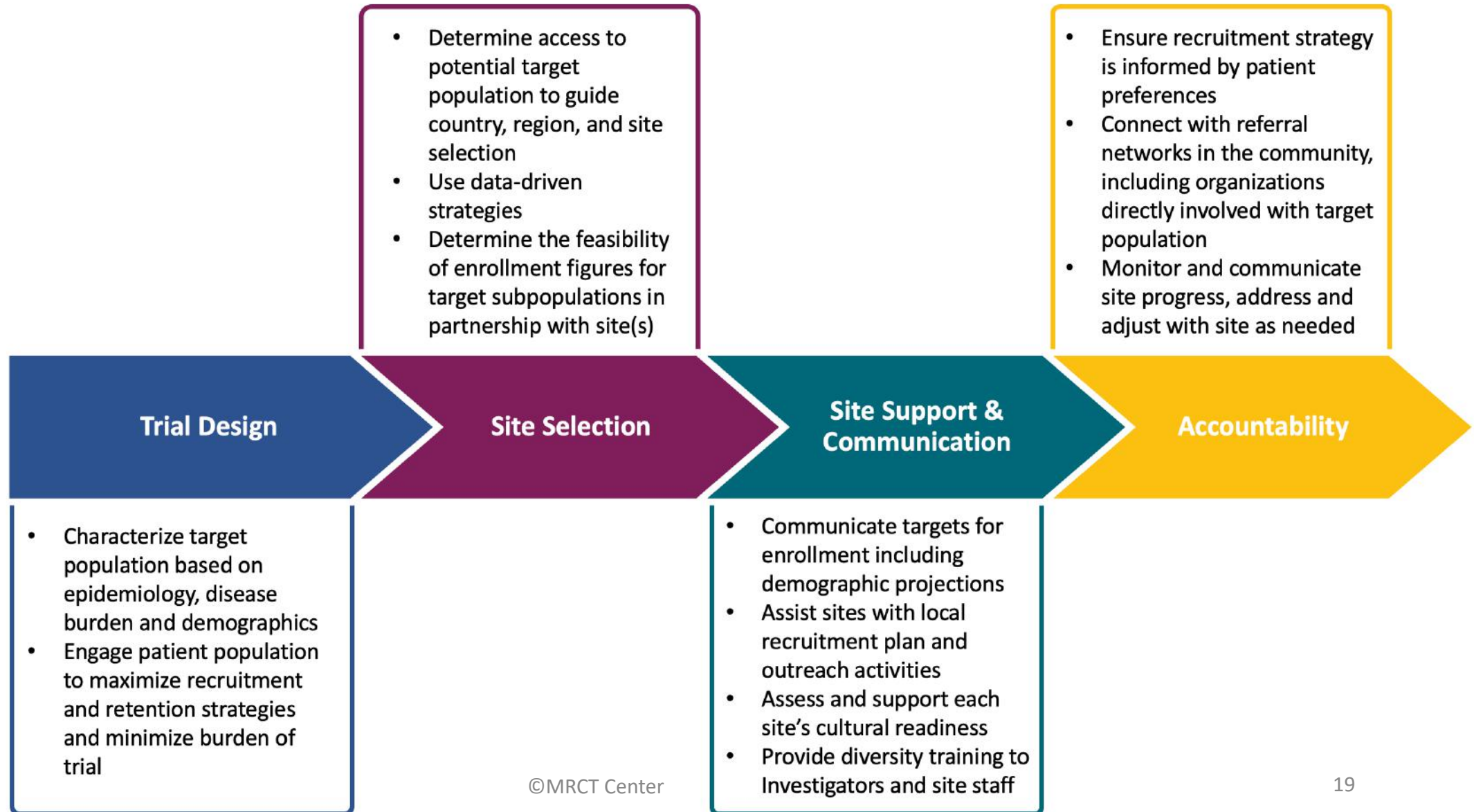


# Product Development Pathway

## DIVERSITY CONSIDERATIONS BY CLINICAL DEVELOPMENT LEVEL



# Opportunities: What can we do?



# Key Sponsor 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

“

*Is there anything that we should understand to make your participation easier?*

”



# Accountability in Partnership



Holding ourselves and one another accountable

- Metrics
- Transparency
- Dialogue

# The work ahead

- What can each of us do now?
  - One step at a time towards change
- Targeted recommendations for special populations
- Additional tools and resources
- 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](https://mrctcenter.org/diversity-in-clinical-trials)



# Leaning in: *Practical Approaches to improving diversity in Clinical trials*

Webinar Topic	Date
Community awareness, access, knowledge	October 14, 2020
Workforce Development	October 28 , 2020
Study Design, Eligibility, Site Selection & Feasibility	November 11, 2020
Study Conduct (Recruitment, Retention)	December 9, 2020
Data Standards and Analysis	January 13, 2021
Stakeholder Roles and Responsibilities	January 27, 2021
Role of Data in Diversity: Genetics & RWD	February 10, 2021

***Leaning in* webinars will be held Wednesdays 11 AM -12 noon ET**





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# Discussion and Questions