



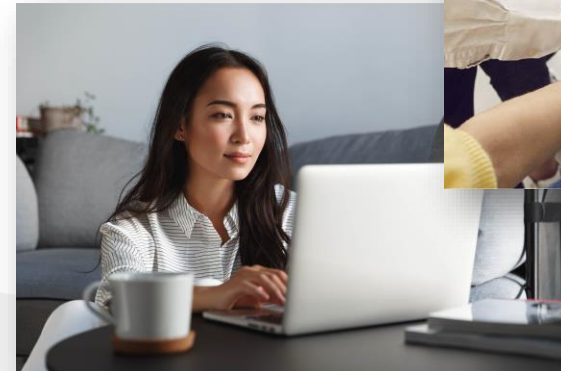
Identifying the approaches and challenges to improving diversity in clinical research

*March 28
Outsourcing in Clinical Trials Southeast 2023
Cary, NC*

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Center for Information and Study on
Clinical Research Participation (CISCRP)

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- Independent, 501(C)(3) non-profit
 - Boston-based
 - Globally active
 - Founded in 2003
-
- ❖ Dedicated to engaging the public and patients as partners in clinical research
 - ❖ Collaborate with foundations, associations, advocacy groups, industry, academic institutions, government agencies



Objectives

- Identifying the approaches and challenges to improving diversity in clinical research
- How patient and community partnership is key to improving DEI
- Fostering collaboration to build public and community trust and engagement
- How regulatory and cross-disciplinary guidance can guide your efforts
- Review concrete examples of diversity initiatives and projects





Definitions & Regulations



“Defining” Diversity, Equity, and Inclusivity

- ❖ Clinical trial diversity is the intentional inclusion of a patient population who differ from each other based on factors such as: Race, Ethnicity, Gender, Age, Sexual orientation, Geographic location, Education level, Socioeconomic status, Health status

- ❖ Health equity happens when everyone has a fair opportunity to attain their highest level of health.

Achieving health equity requires:

- ❖ Acknowledging and addressing historical and contemporary injustices.
- ❖ Overcoming economic, social, and other obstacles to health and healthcare.
- ❖ Eliminating preventable health disparities.

EQUALITY:

Everyone gets the same—regardless if it's needed or right for them.



EQUALITY:

Everyone gets the same – regardless if it's needed or right for them.



EQUITY:

Everyone gets what they need—understanding the barriers, circumstances, and conditions.



EQUITY:

Everyone gets what they need – understanding the barriers, circumstances, and conditions.



an Foundation

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FDORA

Public Law 117-328; Title III--Food and Drug Administration; Subtitle F--Cross-Cutting Provisions; Chapter 1--Clinical Trial Diversity and Modernization

- Signed into Law December 29, 2022
- **Diversity Action Plan Required for Phase 3 Studies and other pivotal studies**
- Device studies are included in the requirement (with exceptions)
- Action plan contains
 - (A) the sponsor's goals for enrollment in such clinical study
 - (B) the sponsor's rationale for such goals; and
 - (C) an explanation of how the sponsor intends to meet such goals, including demographic-specific outreach and enrollment strategies, study-site selection, clinical study inclusion and exclusion practices, and any diversity training for study personnel;**

<https://www.congress.gov/bill/117th-congress/house-bill/2617/text>



Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry

NOVEMBER 2020 (FINAL)

Purpose: “...in part, to satisfy the mandates of the FDA Reauthorization Act of 2017 (FDARA)”

- Broadening **eligibility criteria** to increase diversity in enrollment
- Make **trial participation less burdensome** for participants
- Adopt **enrollment and retention practices** that enhance inclusiveness
- Expanded access

<https://www.fda.gov/media/127712/download>



Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials

APRIL 2022 (DRAFT)

Purpose: “...approach for developing a Race and Ethnicity Diversity Plan”

Describe specific trial enrollment and retention strategies, including but not limited to:

- site location and access** (e.g., language assistance for persons with limited English proficiency, reasonable modifications for persons with disabilities, and other issues such as transportation);
- sustained community engagement** (e.g., community advisory boards and navigators, community health workers, patient advocacy groups, local healthcare providers, etc.);
- reducing burdens due to trial/study design/conduct** (e.g., number/frequency of study-related procedures, use of local laboratory/imaging, telehealth);

<https://www.fda.gov/media/157635/download>

Tools & Resources

- Multi-Regional Clinical Trials (MRCT) Center: “Achieving Diversity, Inclusion, and Equity in Clinical Research” Guidance
- MRCT Website with toolkit and case studies
- EMPACTA and similar publications on achieving DEI in trials

<https://mrctcenter.org/diversity-in-clinical-research/wp-content/uploads/sites/11/2021/09/MRCT-Center-Diversity-Guidance-Documents-Version-1.2.pdf>
<https://mrctcenter.org/diversity-in-clinical-research/>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8785867/>

RECOMMENDATIONS FOR THE FUTURE OF CLINICAL TRIALS

Based on the collaborative efforts between Genentech and the External Council, we have several key system-, study-, and patient-level recommendations for future clinical trials to improve the diversity of their patient enrollment

SYSTEM LEVEL

Addressing the barriers that currently prevent participation requires significant investment in health care infrastructure and policy reforms to build trust and promote greater inclusivity within clinical research.

PATIENT LEVEL

We believe it is incumbent on industry to help patients overcome the mistrust, lack of awareness, and financial barriers that contribute to the dearth of diverse clinical research participation. Thus, the following patient-level suggestions are implemented by sponsors and health care industry partners in support of patients.

STUDY LEVEL

Multilevel strategies across the life sciences industry are needed to modernize clinical development programs to lower costs, expand access and enhance patient participation from minority communities.

INVEST IN & PRIORITIZE THE DEVELOPMENT OF PROGRAMS TO INCREASE DIVERSITY
of medical professionals

SHOW UP EARLY IN COMMUNITIES & BUILD TRUST
through sustained engagement with community stakeholders & patient advocacy groups

STUDY SPONSORS SHOULD PRIORITIZE INCLUSIVE RESEARCH
& tailor strategies to achieve this objective

PRIORITIZE NEW HEALTH EQUITY EDUCATION PROGRAMS
in medical schools & with practicing clinicians

FACILITATE OUTREACH & AWARENESS PROGRAMS IN UNDERREPRESENTED COMMUNITIES
(including health literacy and health equity programs)

CAREFULLY EVALUATE INTERNAL PROCESSES FOR BIAS
(eg. study protocols, contract language, enrollment targets, informed consents translated to multiple languages)

ENSURE POLICIES ADDRESS LACK OF PATIENTS' ACCESS
to internet, phones, computers & education on how to use these technologies

MAKE TRIALS MORE ACCESSIBLE BY COVERING OUT-OF-POCKET PATIENT COSTS
(eg. transportation, missed work, child care)

MAKE TRIALS MORE PATIENT-CENTRIC
by going to sites where minority patients are typically seeking health care (ie, find novel clinical trial sites in the community and in rural areas)

RAISE AWARENESS ON THE NEED FOR INNOVATIVE HEALTH CARE POLICIES
to address patient clinical trial benefits

RETURN TO PARTICIPATING COMMUNITIES AT TRIAL CONCLUSION
& provide trial results on how their efforts contributed to scientific advancement

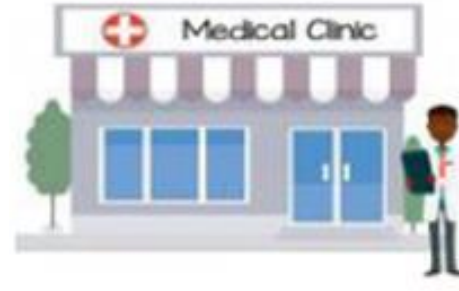
INVEST IN TRAINING CROs & SITES ON HOW TO ENGAGE PATIENTS OF COLOR
about a clinical trial

EDUCATE PATIENTS ON THE BENEFITS OF CLINICAL RESEARCH PARTICIPATION
& the future of personalized health care

EMBRACE TELEMEDICINE & MOBILE TECHNOLOGIES
to provide the basis for remote or decentralized clinical trials

EMBRACE SHARED DECISION-MAKING
to allow patients time to discuss trial enrollment with family members

ADVANCING
INCLUSIVE
RESEARCH®



“Global Investigative Site Personnel Diversity and Its Relationship with Study Participant Diversity”

Getz, et. al., Ther Innov Regul Sci. 2022 Sep;56(5):777-784. doi: 10.1007/s43441-022-00418-9. Epub 2022 Jun 10.

- address under-representation in clinical trials through **identifying, hiring and supporting investigative site personnel to best reflect the patient communities that they serve**
- **significant correlation between site personnel diversity and patient enrollment diversity** worldwide
- significant relationship between proportion of given **race or ethnicity of investigative site personnel and the corresponding race and ethnicity of patients enrolled**
- highest personnel diversity in private community-based practices, investigative sites and site networks

<https://pubmed.ncbi.nlm.nih.gov/35687265/>





Community Insights & Examples of DEI Education and Engagement Initiatives



Perceptions and Insights Global Surveys



- Measuring Clinical Research Perceptions and Experiences
- 12,400+ respondents globally
 - Past trial participants
 - Members of the public
- Biannual
 - 2021 reports available (4th iteration)



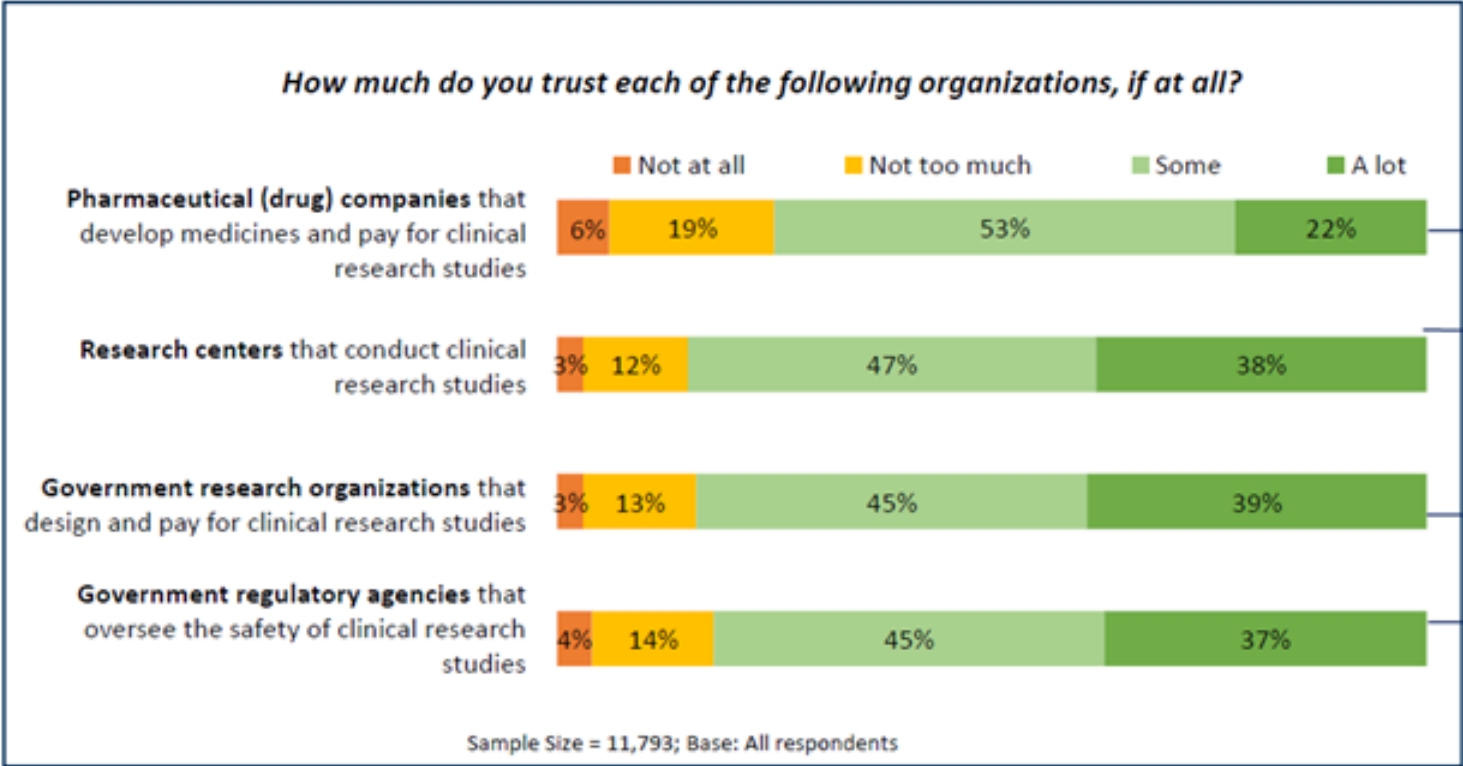
A total of 11,793 respondents completed the survey. Respondent characteristics are as follows:

Gender	51% Female 45% Male 4% All other genders
Region	69% North America 3% South America 19% Europe 6% Asia-Pacific 3% Africa
Age	31% 18 - 34 years old 16% 35 - 44 years old 14% 45 - 54 years old 18% 55 - 64 years old 21% 65 or older
Race	74% White 7% Black or African American 5% Asian
Ethnicity	72% Non-Hispanic 28% Hispanic
Incidence of participation in a clinical trial	53% have never participated 47% have participated

Building Trust Remains a Top Objective

While the public's trust in research centers/clinics, government research organizations, and regulatory agencies increased since 2019, trust in pharmaceutical companies remains low.

PUBLIC TRUST

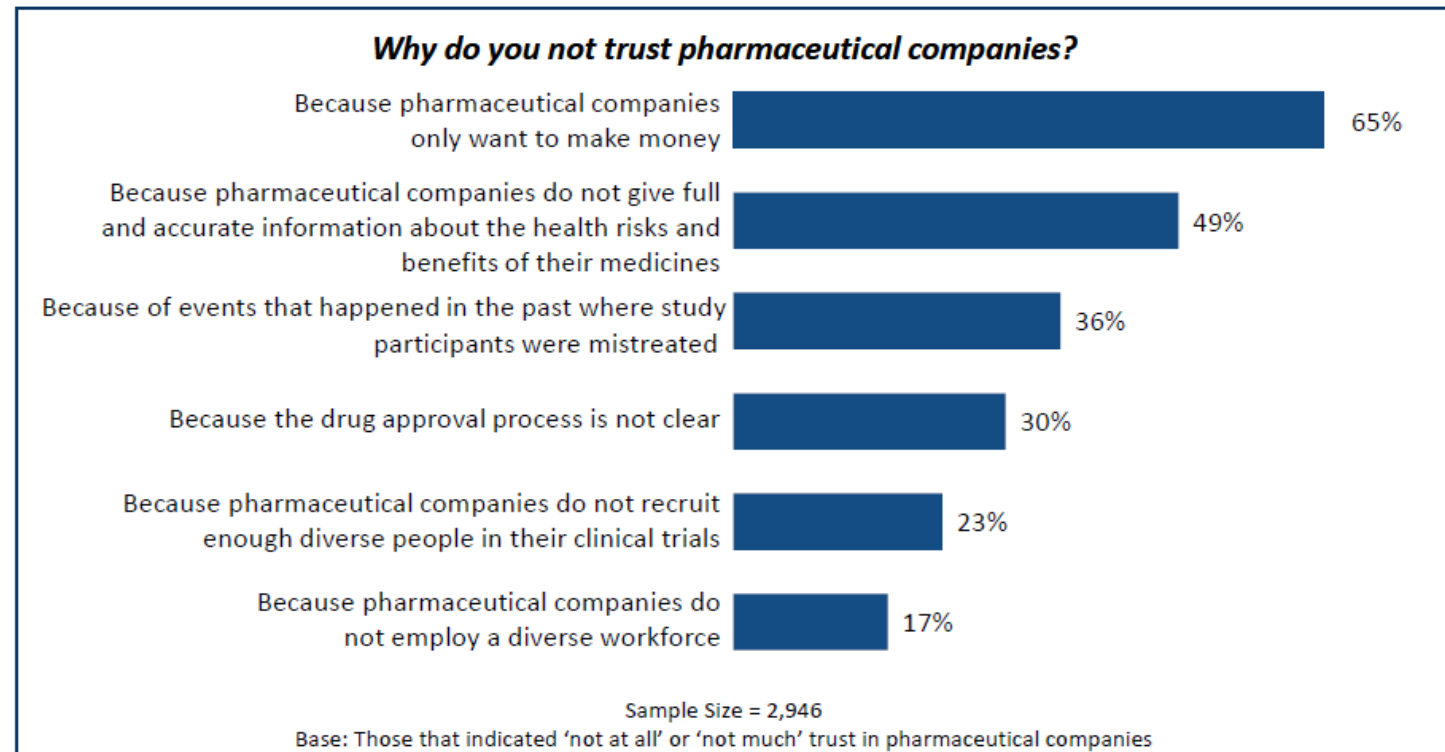


South American respondents (32%) were significantly more likely to cite trusting pharmaceutical companies 'A Lot' compared to all other regions (19-22%). African respondents (25%) were less likely to report trusting government research organizations than those in any other region (34-42%).

Reasons for Lack of Trust

Financial motivations, withholding information about health risks, and past mistreatment of clinical research participants are cited as the top reasons respondents do not trust pharma

INCREASING TRUST IN PHARMACEUTICAL COMPANIES



- **Black respondents were more concerned than any other race about past events where participants were mistreated (47%)**
- **White respondents were distrustful due to pharma's focus on money (72%) more than other racial groups (47-51%)**



Awareness: learn and understand the audiences' attitudes and values



Competency: match the audiences' Logic, Language, & Experience (LLE)

- **Logic:** recognize attitudes and beliefs, address misconceptions with educational messages
- **Language:** phrases and terms familiar to the audience can be used if appropriate and related to technical terms
- **Imagery:** sensitive and positive
- **Experience:** provide examples, model ideal behaviors, and ensure the recommended behaviors are realistic



Humility: Examining the effect of one's own attitudes and values

- Towards the recommended behavior
- Towards the target audience: implicit bias testing



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IT STARTS WITH

ONE

For Us, With Us

- ✓ Co-development with community members and subject matter experts who have experience working with those communities
- ✓ User-testing via anonymous survey of 500 community members
 - ✓ Diversity of ethnic and racial, genders and socioeconomic backgrounds
- ✓ Culturally relevant and competent topics, language, images, and design
- ✓ Address communities' key concerns and barriers to participation



Kids are people too! Pediatric Inclusion



Your clinical study

Their mother

Sara

Alex

As Sara and her family walked from the train to the doctor's office, she asked her brother, "Alex, did you know that I'm a medical hero?"

"Wow!" said Alex. "You are?!"

"That's right, your sister is a **medical hero!**" said their mother.



Hard to breathe

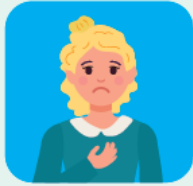


Chest tightness

People with asthma sometimes find it hard to breathe or feel chest tightness



Coughing



Wheezing

Asthma can make people cough or wheeze



Hard to sleep

Sometimes asthma can make it hard to sleep at night

Clinical Study Results

Why the research was needed

"I have asthma," explained Sara. "Asthma makes it hard for me to breathe sometimes, or makes me cough or wheeze. It also can stop me from doing things like playing soccer. Sometimes, asthma can even make it hard to sleep at night. I helped my research team study a new medicine for asthma."

"I thought you already take asthma medicine," said Alex.

"Yeah, I do. But, that medicine doesn't always make me feel better. That's why we're trying to find out if a new medicine can help more."



Acronym or study name | DRAFT_POC

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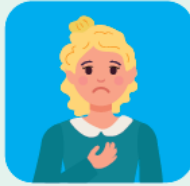


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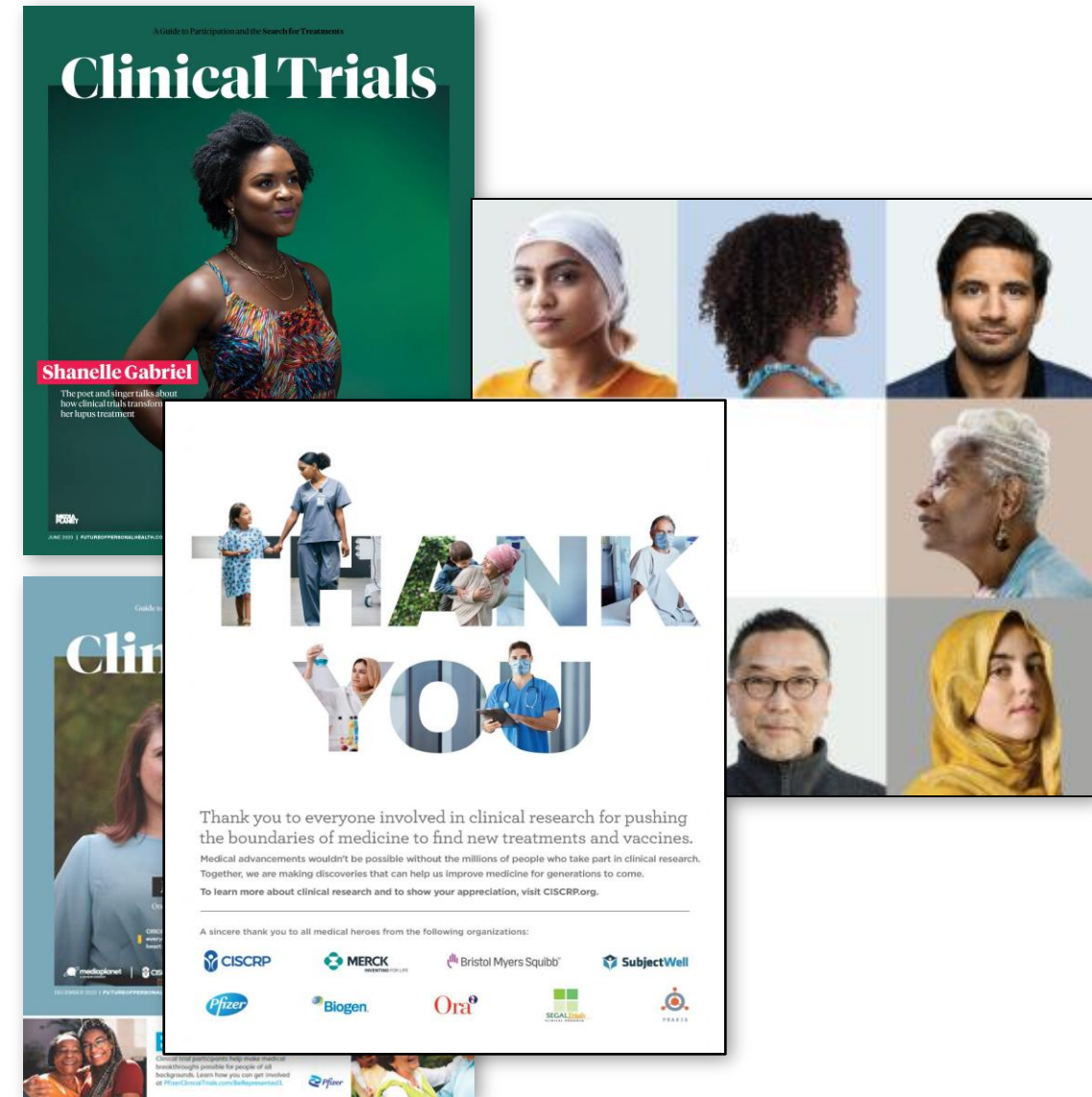
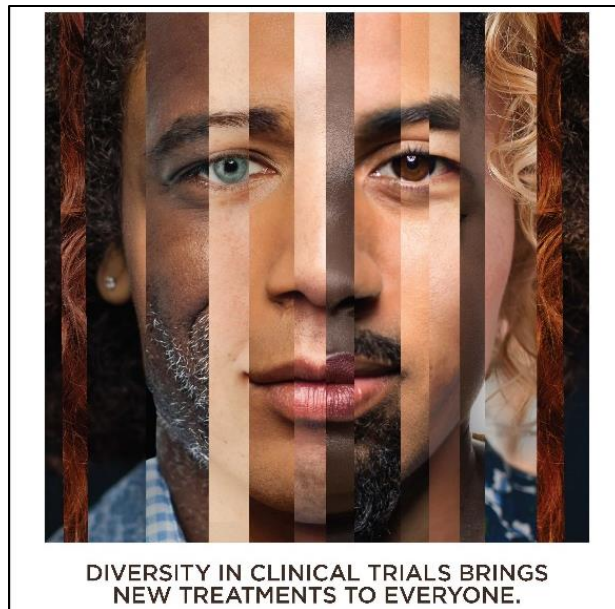


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Outreach and Awareness

- ✓ Highlight the critical importance of patient diversity and inclusion within clinical trial participation
- ✓ Enhance public awareness, literacy and understanding of clinical research with educational articles/ads
- ✓ Improve public perception about clinical research study participants

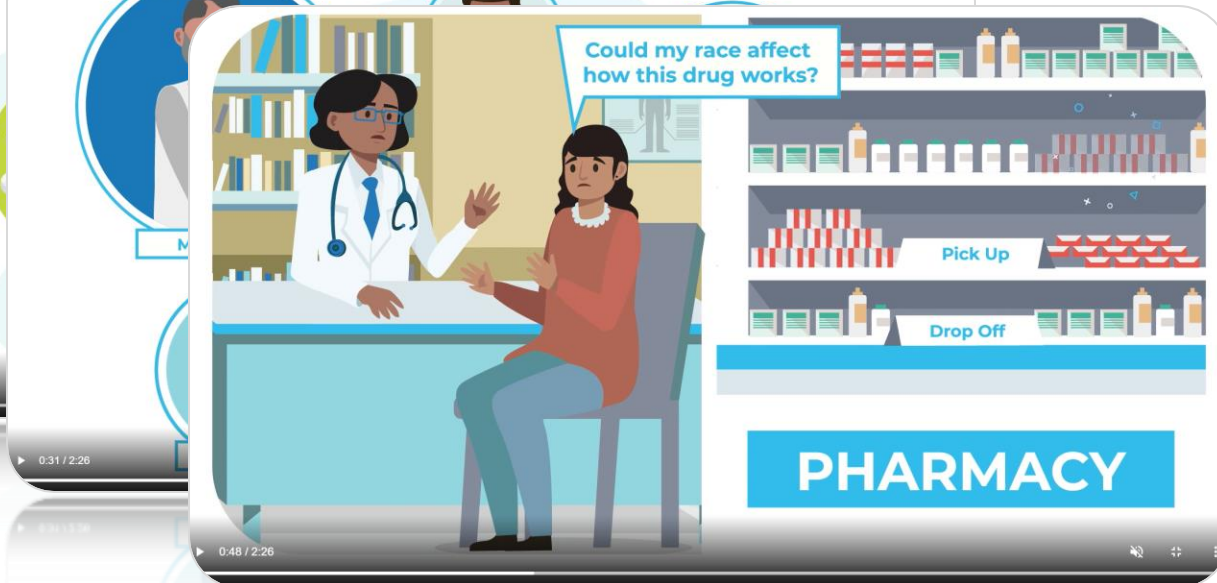


Investigator/Site Education & Training



Improve awareness, knowledge and skills with workshops, webinars, videos, infographics

- Diversity, Equity, and Inclusivity (DEI) Awareness
- DEI and Cultural Competency Practices
- Health Literacy Techniques for Informed Consent Process
- Patient Engagement Practices to Improve Recruitment & Retention

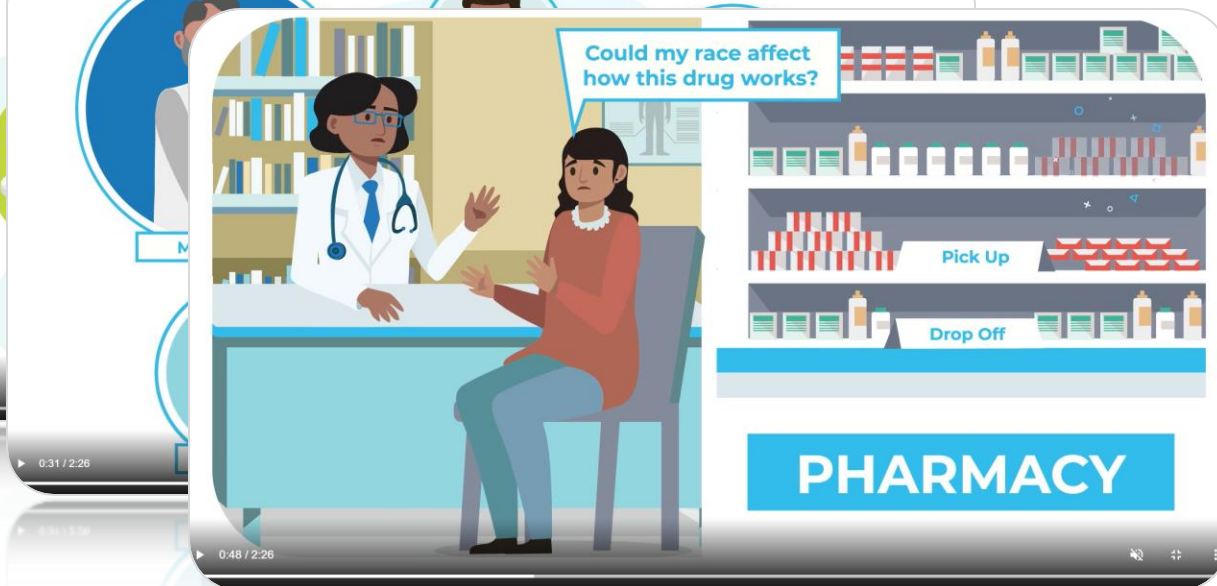


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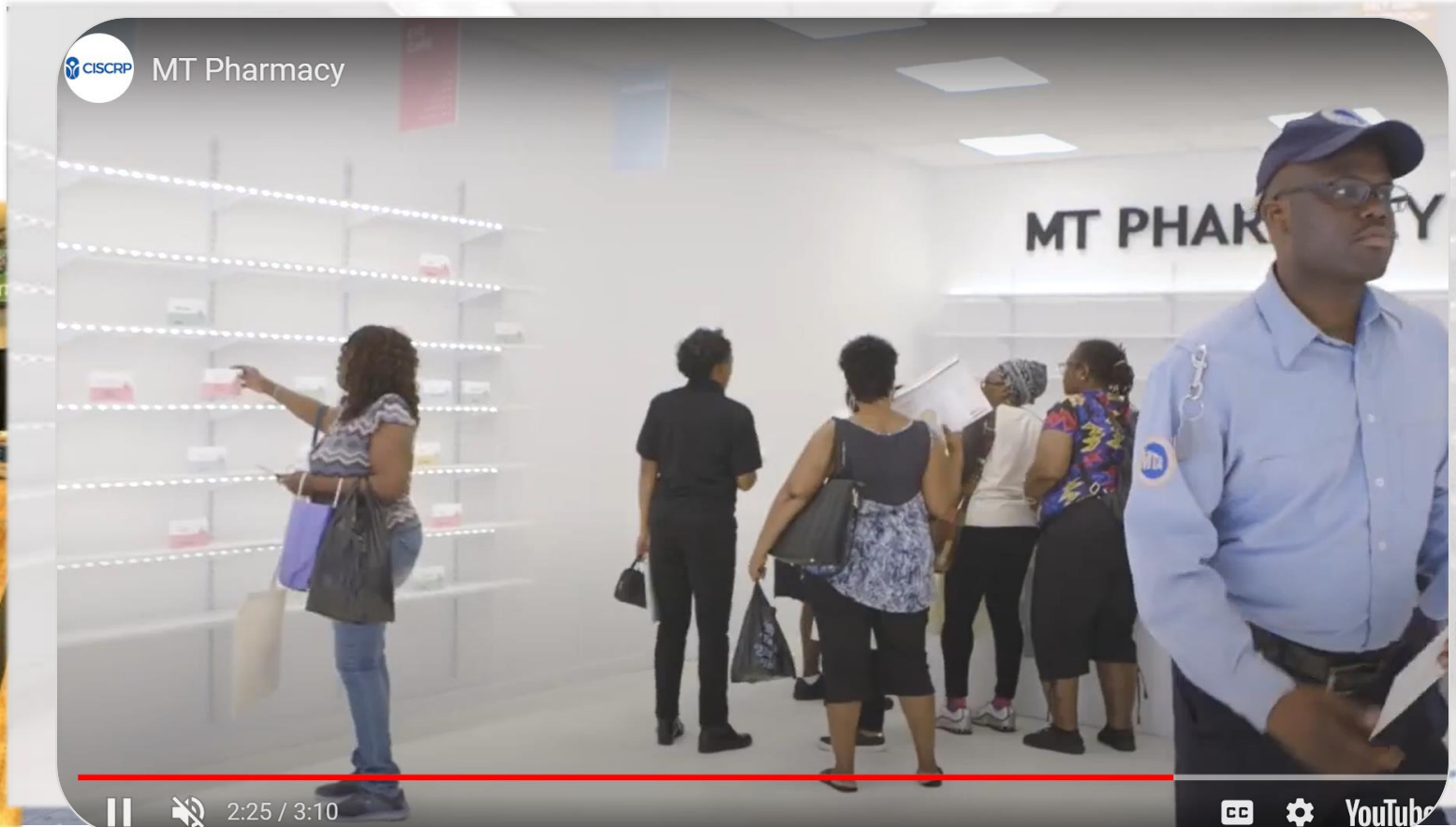
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Innovative Engagement

Grass-roots campaigns to engage and educate patients and the public in clinical research

- ✓ Live Education Events
- ✓ MT Pharmacy



Journey to Lasting Impact



2018

- "Journey to Better Health RV"
- Los Angeles
- Identify and train community educators
- Improve education event registration

2023+

- FDA's Office of Minority Health and Health Equity Innovation AWARD
- "Evaluating Impact of Mobile Community Education Engagement Initiative..."
- Philadelphia & Baltimore
- Partner with community leaders
- Collaborate with organizers of existing events to enhance receptivity and impact



IMPORTANCE OF DIVERSITY IN CLINICAL RESEARCH

Everyone needs to be included, including your community.

Treatments and vaccines might not work the same in people of different races, ethnicities, ages, or sexes. To find treatments and vaccines that work and are safe for everyone, people from all backgrounds need to be represented in clinical research.

Addressing Injustice

It's important that we recognize past and current injustices in clinical research. People from underrepresented communities are not always made aware of opportunities to participate and have been mistreated in clinical research.

Mistreatment in clinical research has led some to mistrust doctors, researchers, and the healthcare system. This causes some people to avoid being a part of clinical research.



Tuskegee Study, 1932 to 1972

In this study, researchers withheld a treatment for syphilis from Black male participants to learn what happens when syphilis went untreated.



Contraceptive trials in Puerto Rico, 1955 to 1956

Researchers gave untested birth control pills to Puerto Rican women specifically because they were seen as poor and uneducated. They were not told that it was part of a clinical trial and that the pills had potentially dangerous side effects.



Henrietta Lacks, 1920 to 1951

Doctors and researchers shared cancerous cells collected from Henrietta Lacks, a Black woman, without her knowledge or consent. Lacks' cells ("HeLa cells") became an important tool in biomedical research and were shared widely among the scientific community for profit, none of which went to her family. For decades after her death, Lacks' private medical information was shared publicly without consent from her family.

in your community





Thank you!



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