DEI SYMPOSIUM
WELCOME & INTRODUCTION

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ACCP
American College of Clinical Pharmacology®
Advancing Clinical Care through Pharmacology®

2022 ACCP Annual Meeting
Transforming Global Health through Clinical Pharmacology

Equity and Diversity in Clinical Research and Development: Addressing Disparities and Barriers to Improve Medication Access.

- Why this session?
- Why now?

Drug Development and Medication Access for ***ALL of US***

https://nigms.nih.gov/education/fact-sheets/Pages/pharmacogenomics.aspx

Alignment with ACCP's Mission and Vision.

… generation, integration and translation of scientific knowledge to optimize the research, development and utilization of medication for the ***benefit of all****.*

Regulatory and Ethical Considerations.

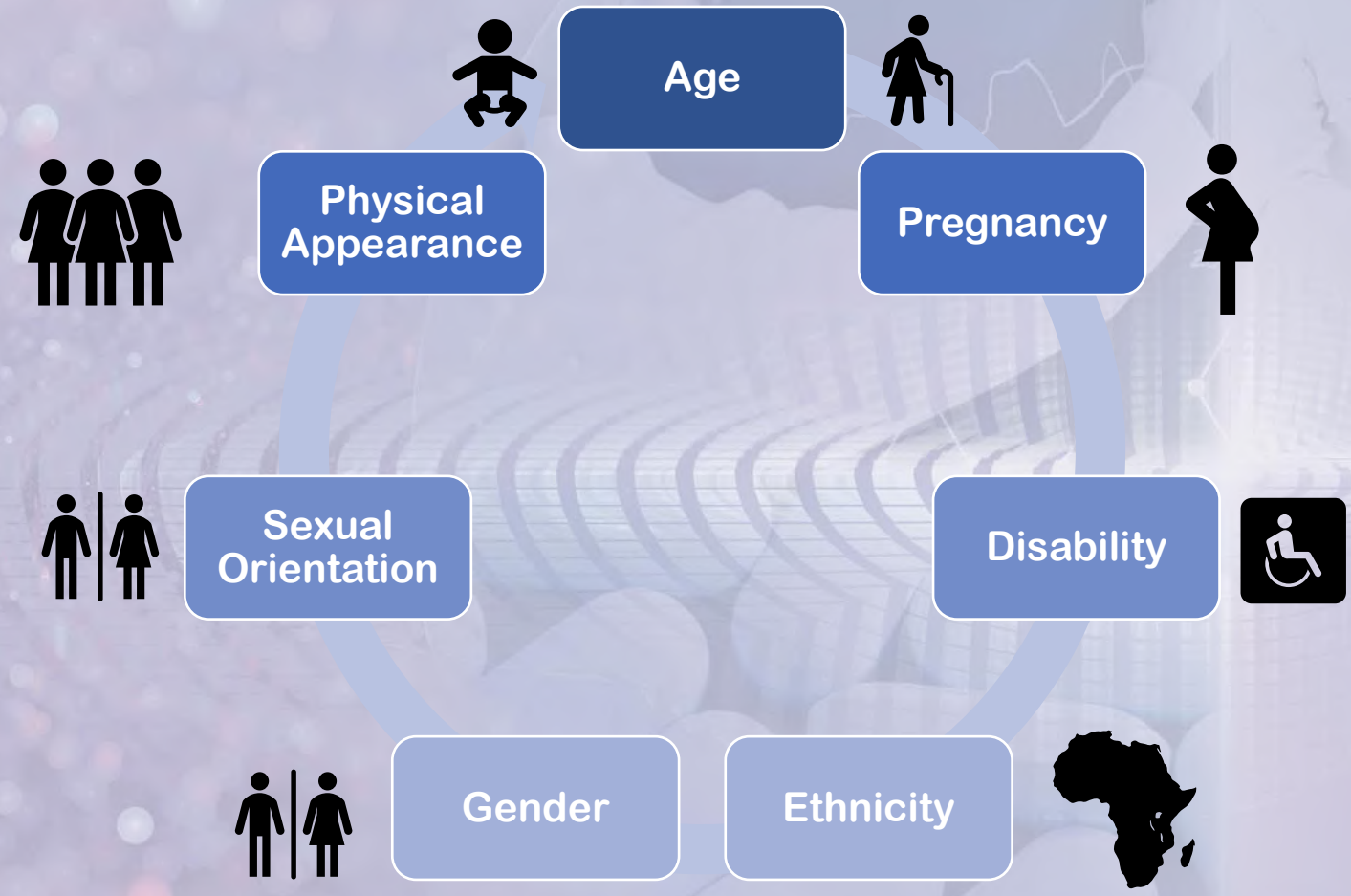
Belmont Report — Beneficence and Justice

Helsinki Declaration

FDA Initiatives and Draft Guidances

- Drug Trials Snapshot (2015)
- Collection of Race and Ethnicity Data in Clinical Trials (2016)
- *Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry* (2022)*

Bridge the Gap. Meet the Need(s)



Diverse Perspectives

- Regulatory —
- Industry —
- Patient —
- Academia —

Equity and Diversity in Clinical Research and Development: Addressing Disparities and Barriers to Improve Medication Access.

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Importance of Diversity During Development and Approval of Novel New Drugs

Anuradha (Anu) Ramamoorthy, PhD, FCP
Policy Lead, Guidance and Policy Team
Office of Clinical Pharmacology (OCP)/OTS/CDER/OMPT/FDA

2022 ACCP Annual Meeting

Topics for Today

- **What** does diversity mean in the context of drug development and approval?
- **Why** does diversity matter?
- **How** can we collectively improve diversity?
  - Eligibility criteria
  - Trial design
  - Other considerations
- Summary

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Inclusion of ALL Clinically Relevant Populations

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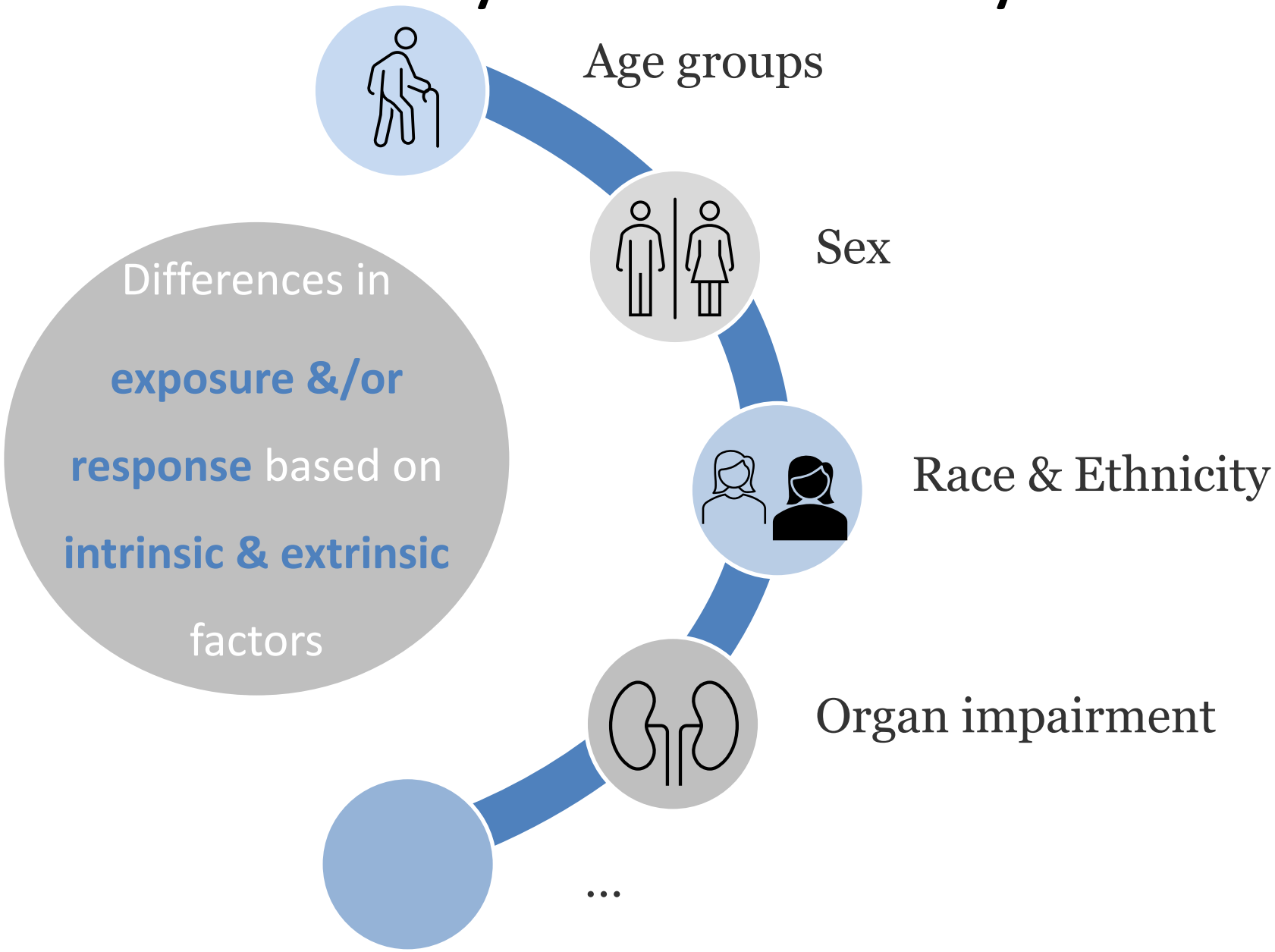
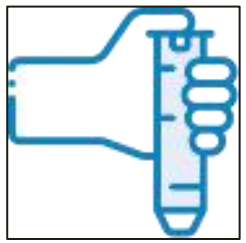
Why Does Diversity Matter?



Labeling Recommendation Availability for Subpopulations

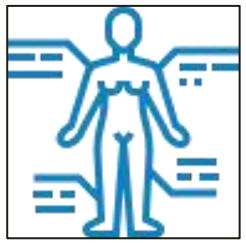


No dose adjustment
No special monitoring recommendations

Different dosing recommendations

Recommendations for considering alternative therapies

Warnings and Precautions



Indication/Contraindication

Postmarketing Studies to Obtain Additional Information on Safety, Efficacy, or Optimal Use

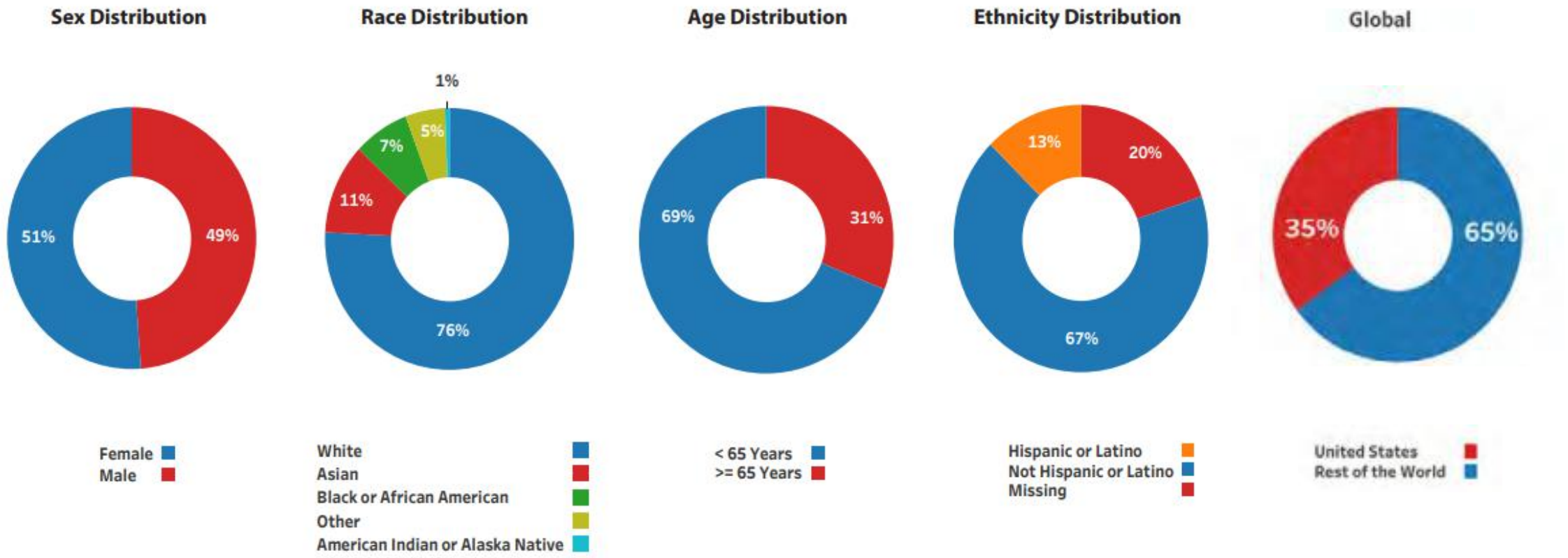
Conduct a randomized, controlled clinical trial to evaluate the efficacy and safety in **African-American patients** with systemic lupus erythematosus (belimumab, 2011)

Conduct a lactation study in **lactating women** to assess concentrations in breast milk using a validated assay (daridorexant, 2022)

Conduct a study to provide evidence characterizing the safety in patient who are **65 years of age and older** (moxetumomab pasudotox, 2018)

Conduct a clinical pharmacokinetic trial to determine an appropriate dose to minimize toxicity in patients with **severe hepatic impairment** (cenobamate, 2019)

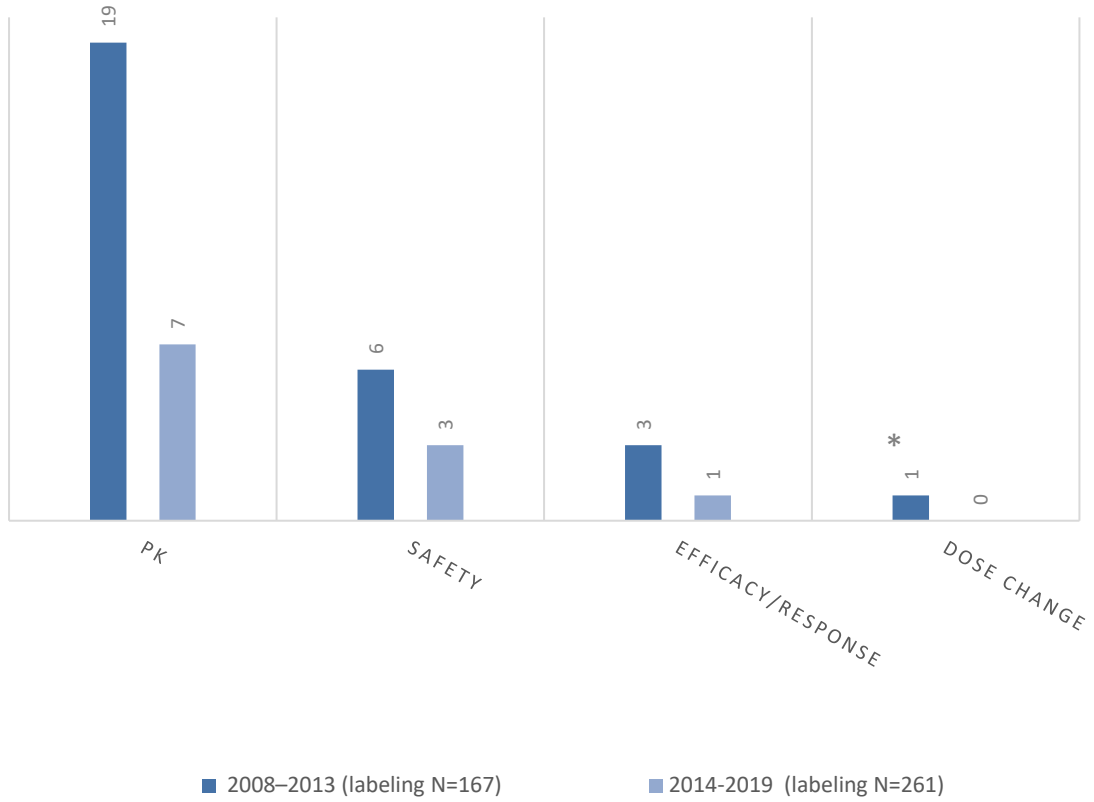
Representation by Various Demographic Subgroups



Source: Drug Trials Snapshots (2015-2019)

Racial/Ethnic Differences Reported for FDA-approved New Drugs

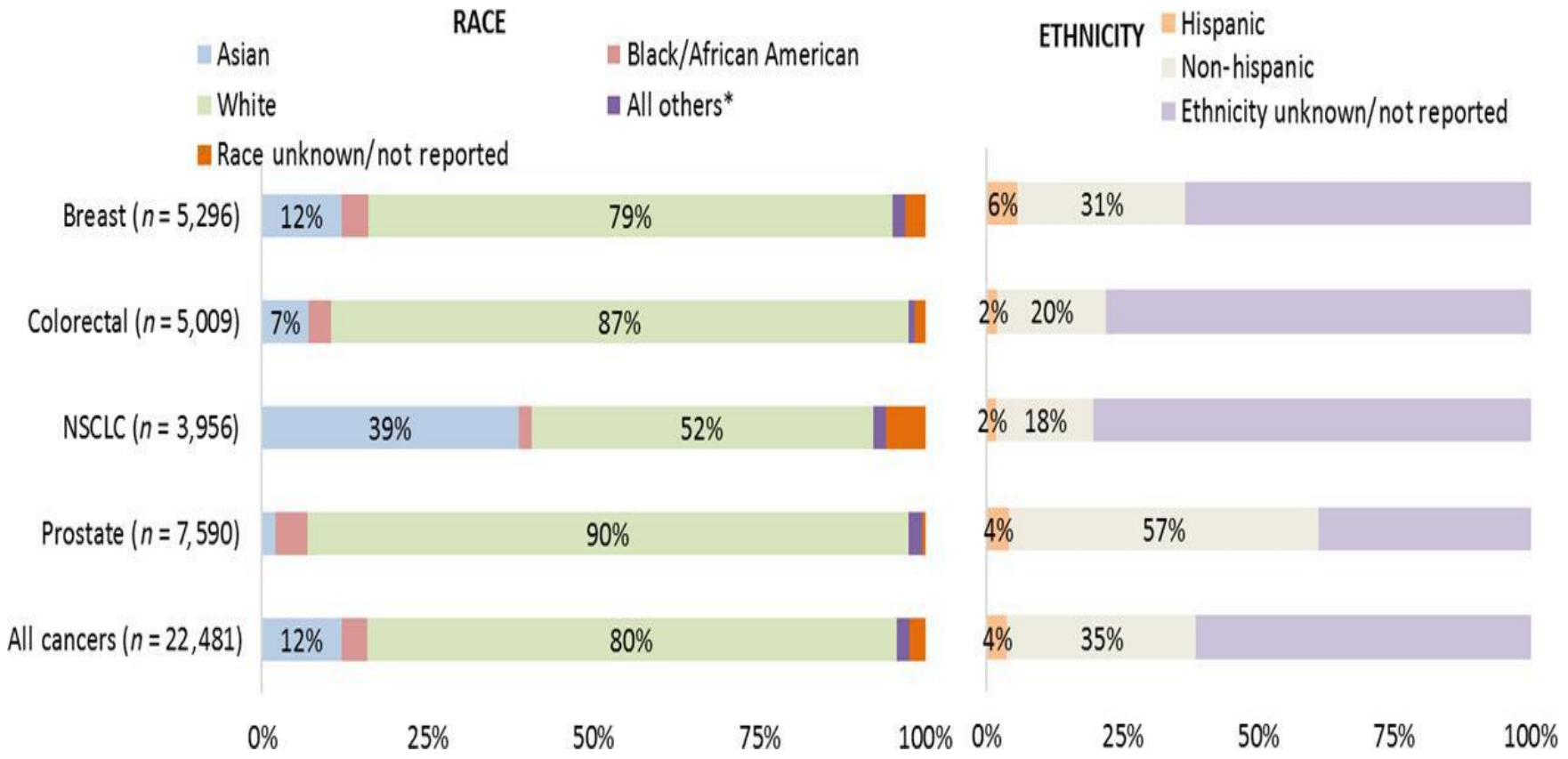
About **1 in 10** novel new drugs had some racial/ethnic differences in **exposure and/or response**



Modified from: Ramamoorthy et al., 2014 & Ramamoorthy et al., 2021; * dose difference subsequently resolved

Demographic Composition of Select Oncologic New Molecular Entities

Low enrollment of racial/ethnic minorities in cancer clinical trials

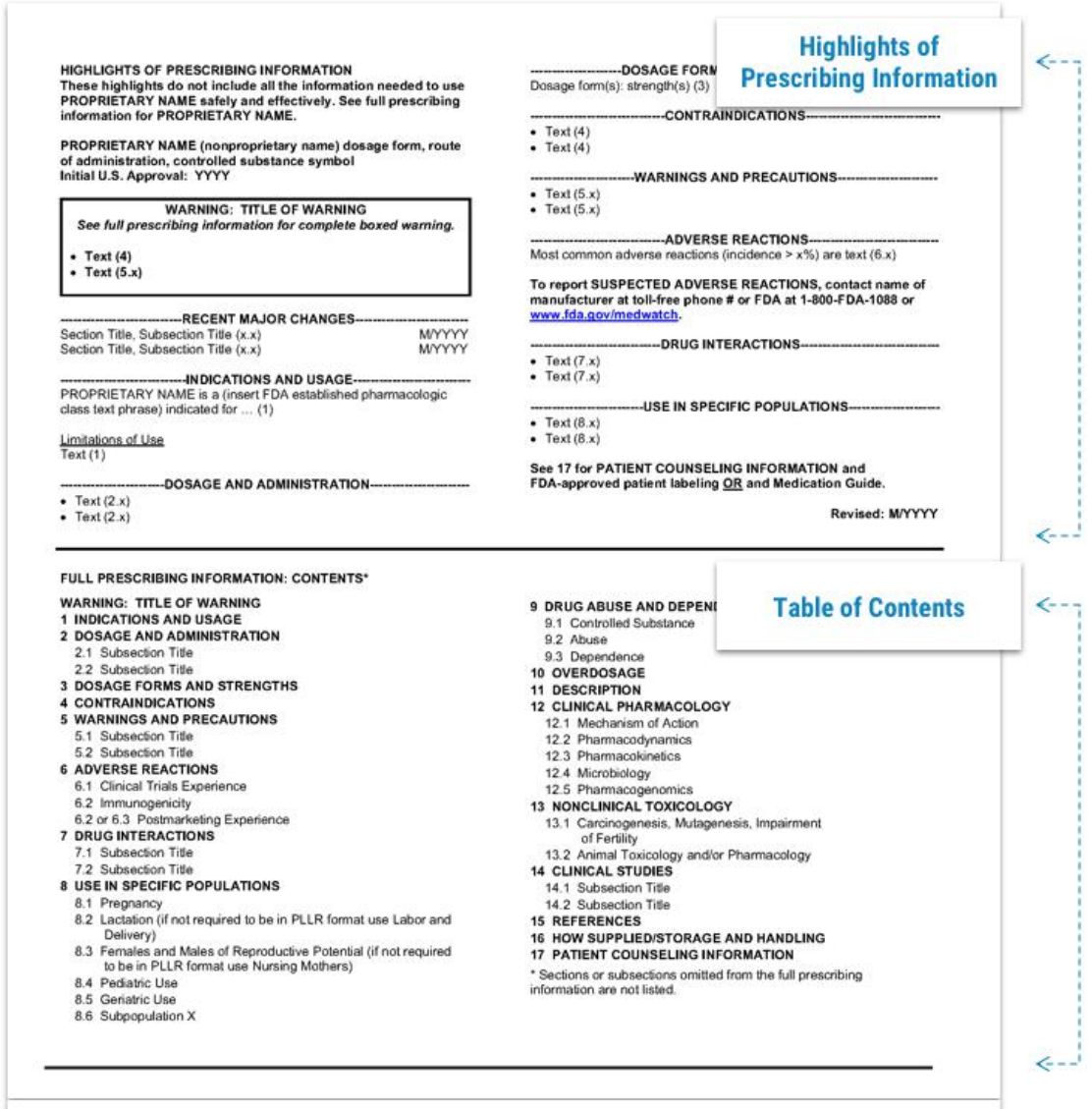


Ref: Ramamoorthy et al., 2018

Why Does Diversity Matter?

Availability of recommendations for use

for ALL clinically relevant subgroups
who will receive the drug upon approval



HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use PROPRIETARY NAME safely and effectively. See full prescribing information for PROPRIETARY NAME.

PROPRIETARY NAME (nonproprietary name) dosage form, route of administration, controlled substance symbol
Initial U.S. Approval: YYYY

WARNING: TITLE OF WARNING
See full prescribing information for complete boxed warning.
- **Text (4)**
- **Text (5.x)**

----------RECENT MAJOR CHANGES----------
Section Title, Subsection Title (x.x) M/YYYY
Section Title, Subsection Title (x.x) M/YYYY

----------INDICATIONS AND USAGE----------
PROPRIETARY NAME is a (insert FDA established pharmacologic class text phrase) indicated for … (1)

Limitations of Use
Text (1)

----------DOSAGE AND ADMINISTRATION----------
- Text (2.x)
- Text (2.x)

----------DOSAGE FORM
Dosage form(s): strength(s) (3)

----------CONTRAINDICATIONS----------
- Text (4)
- Text (4)

----------WARNINGS AND PRECAUTIONS----------
- Text (5.x)
- Text (5.x)

----------ADVERSE REACTIONS----------
Most common adverse reactions (incidence > x%) are text (6.x)

To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- Text (7.x)
- Text (7.x)

----------USE IN SPECIFIC POPULATIONS----------
- Text (8.x)
- Text (8.x)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling OR and Medication Guide.

Revised: M/YYYY

Highlights of Prescribing Information

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

Table of Contents

https://www.fda.gov/about-fda/oncology-center-excellence/how-do-i-use-prescription-drug-labeling

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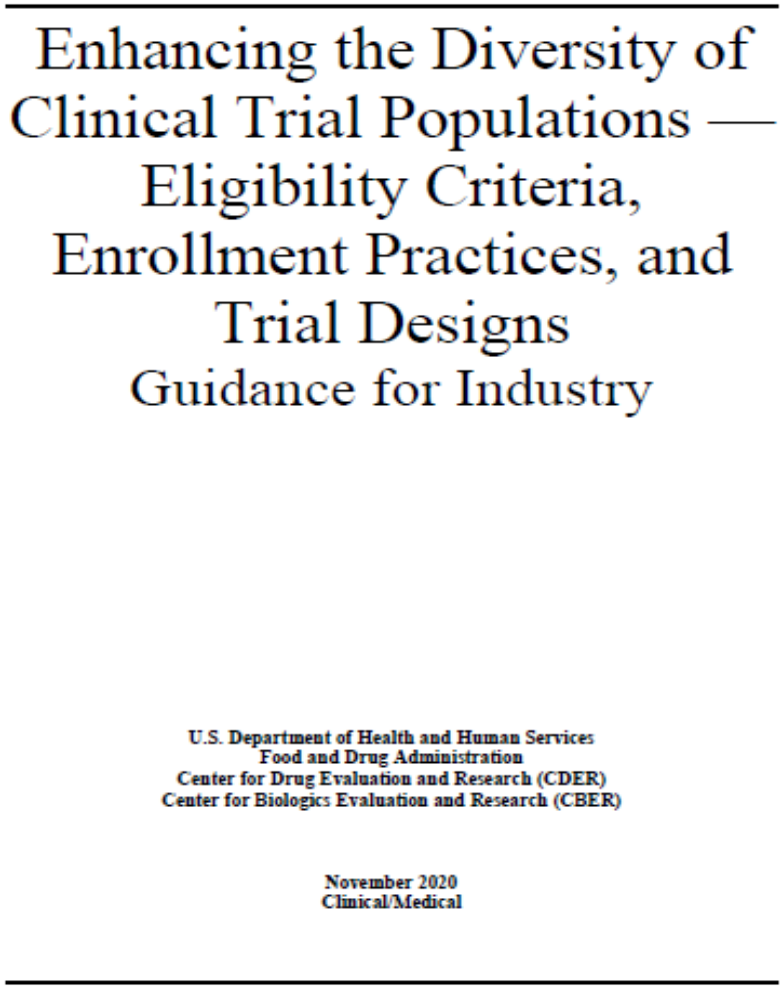
Broadening Eligibility Criteria to Increase Diversity in Enrollment

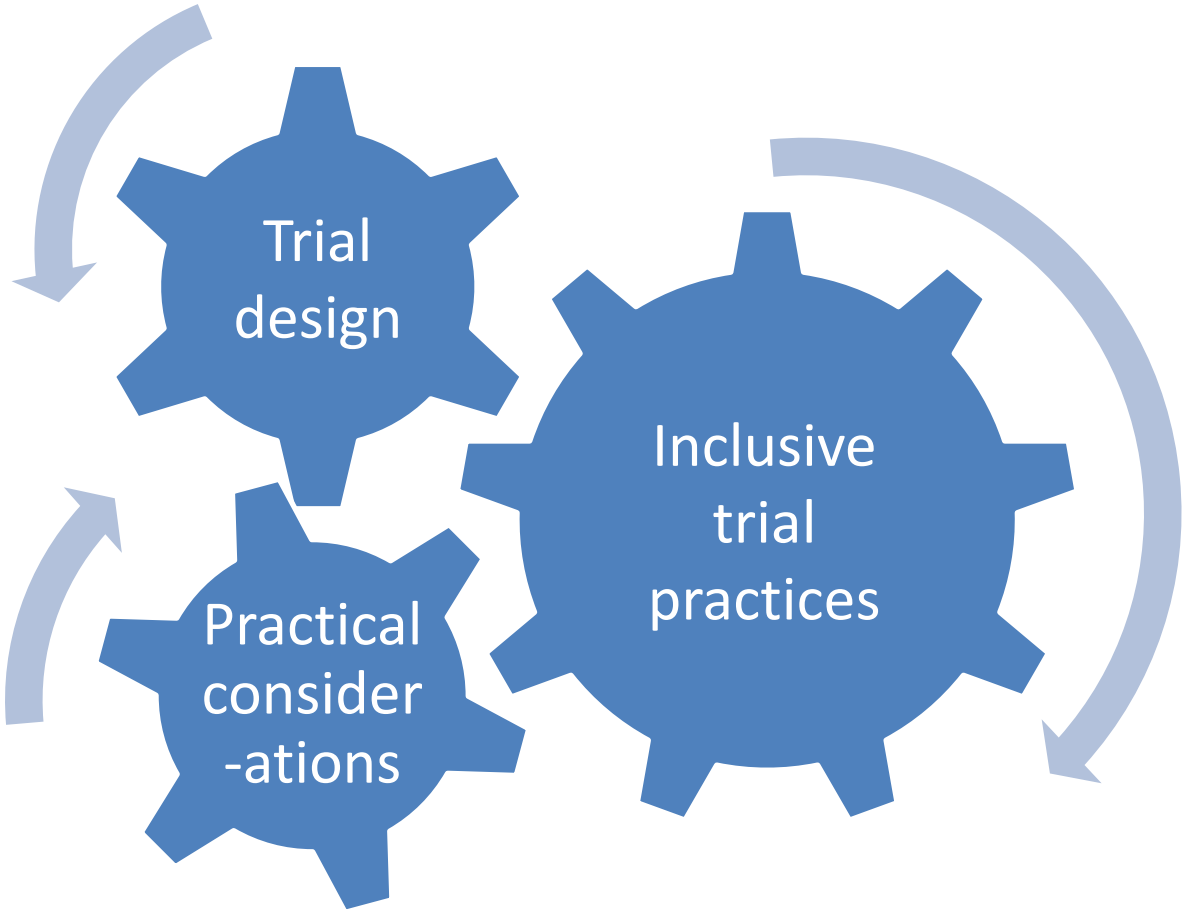


Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

November 2020
Clinical/Medical



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

Inclusive Trial Practices: Eligibility criteria & Enrollment

Evaluation of **exclusion criteria**

Avoid unnecessary carry over of templated exclusion

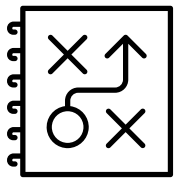
Enrollment of clinically relevant population:

- Age (children, adolescents, older adults
- Sex
- Race and ethnicity
- Organ function
- …

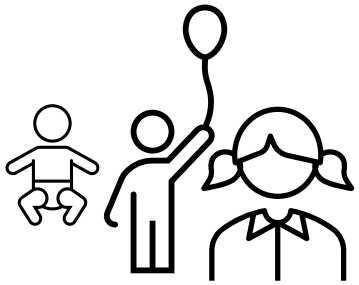
Ref: Eligibility criteria guidance

Trial Design and Methodological Approaches

Characterizing drug metabolism and clearance across populations in early clinical development



Using an adaptive clinical trial design to allow for pre-specified trial design changes



Considering a broader pediatric development program early

Considering PK sampling to establish dosing in women who become pregnant during a trial, if continued participation possible

Ref: Eligibility criteria guidance

Practical Considerations for Improving Enrollment

Make trial participation less burdensome for participants

- Trial design considerations
- Recruitment considerations

Adopt enrollment and retention practices that enhance inclusiveness

- Outreach, engagement, education
- Trial site locations

Expanded access

- In limited circumstances to inform clinical development

Ref: Eligibility criteria guidance

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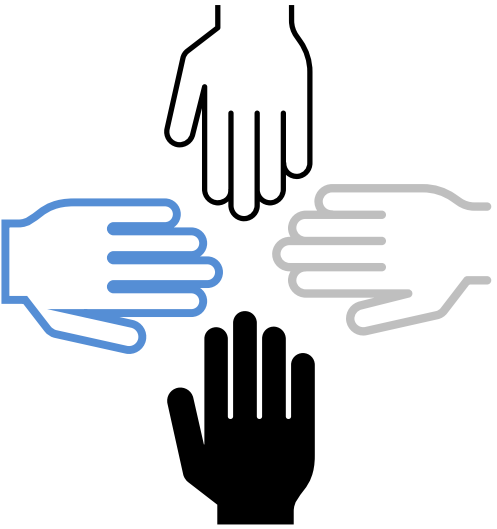

Variability reported for **exposure and/or response** across clinically relevant subpopulations

Diversity is often limited in clinical trials

Need for **continued considerations to enroll underrepresented populations** during drug development and approval

Leveraging **clinical pharmacology** to understand and evaluate the impact of **intrinsic and extrinsic factors** on drug **exposure and response**


Engagement
&
Collaboration

Acknowledgements

- Raj Madabushi
- Elimika Pfuma Fletcher
- Jeff Florian
- GPT
- OCP
- ACCP


FDA
U.S. FOOD & DRUG
ADMINISTRATION

The Challenges and Opportunities for Improving Diversity in Clinical Trials: Perspective from a Drug Developer

Ryan Owen, Ph.D.

Senior Director and Senior Principal Scientist

Genentech Clinical Pharmacology

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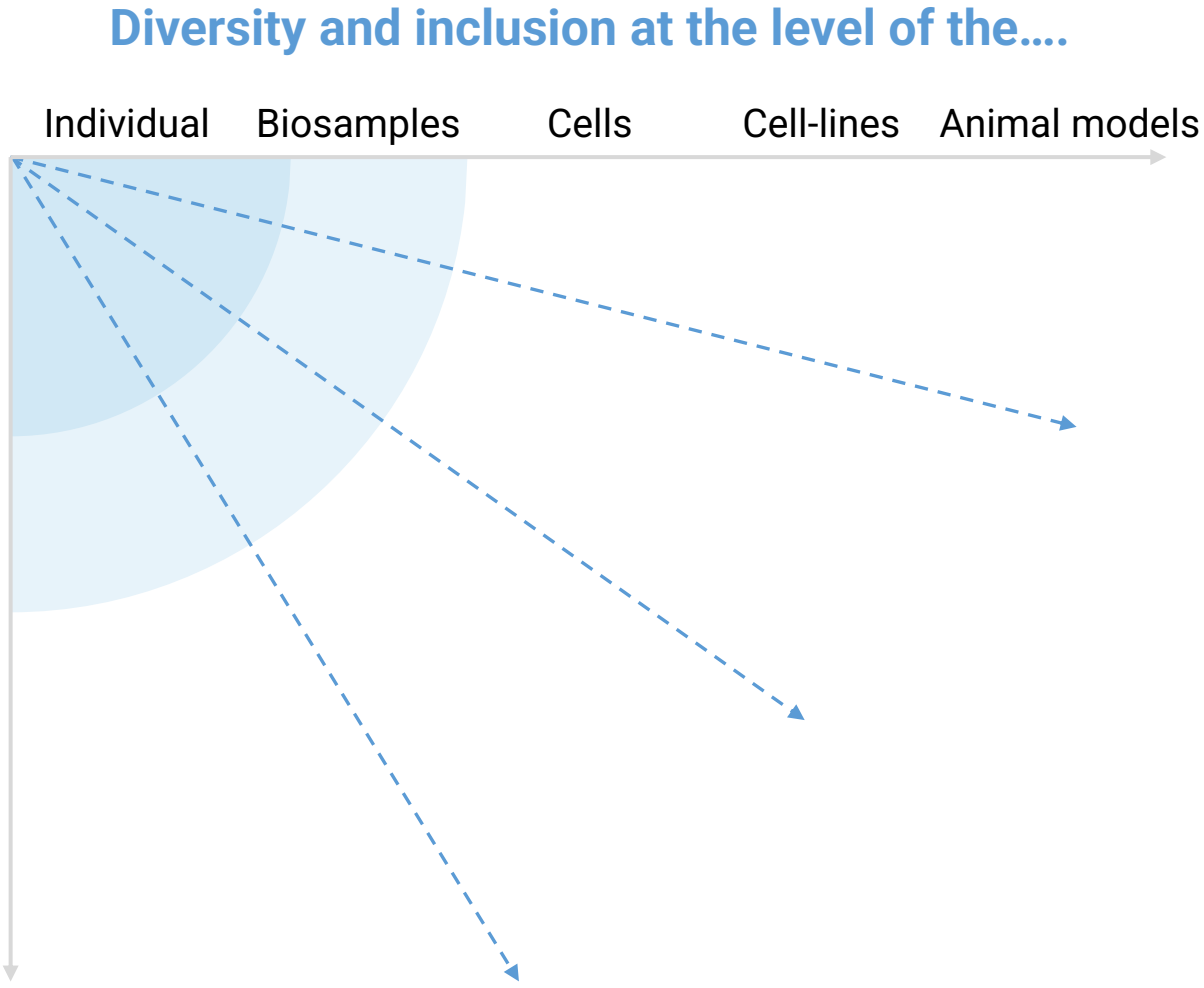
Financial Disclosures

- I am an employee of Genentech, and have stock in the company

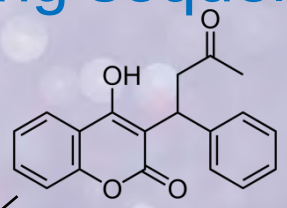
Diversity and inclusion along the axis of….

- Ancestry
- Ethnicity
- Gender
- Income
- Health-care access
- Lifestyle
- Sexuality
- Age



Clinical examples of PGx usefulness

Genetics of PK/PD variability and resulting sequelae



Too much → **Bleeding events**

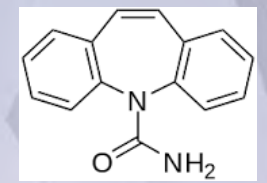
Too little → **MI Stroke**

*CYP2C9*3/VKOR1C -1639 G>A* ⟶ Altered PK/PD

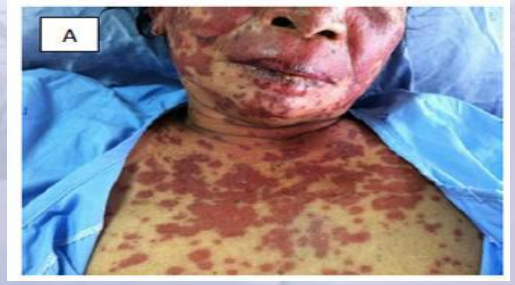
Label language

VKORC1	CYP2C9					
	*1/*1	*1/*2	*1/*3	*2/*2	*2/*3	*3/*3
GG	5-7 mg	5-7 mg	3-4 mg	3-4 mg	3-4 mg	0.5-2 mg
AG	5-7 mg	3-4 mg	3-4 mg	3-4 mg	0.5-2 mg	0.5-2 mg
AA	3-4 mg	3-4 mg	0.5-2 mg	0.5-2 mg	0.5-2 mg	0.5-2 mg

Genetics of adverse events w/ or w/o an underlying PK component



Southern Asian descent → *HLA-B*15:02*



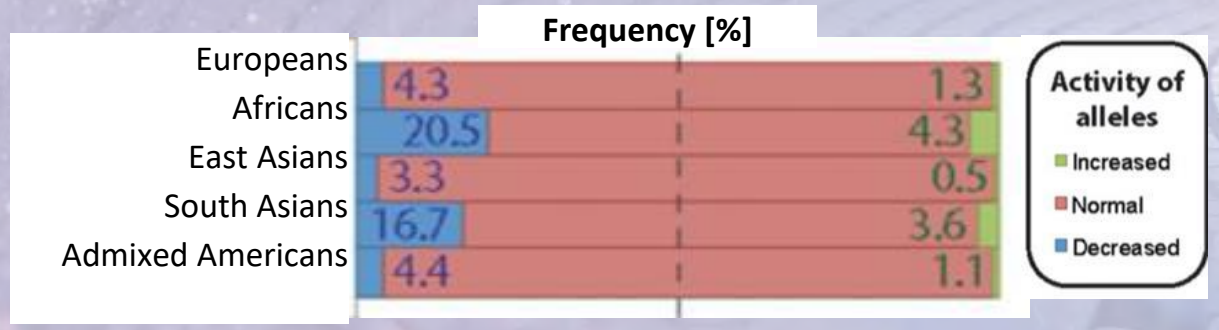
European descent → *No HLA-B*15:02*

Label language: *"Carbamazepine should not be used in patients positive for HLA-B*15:02"*

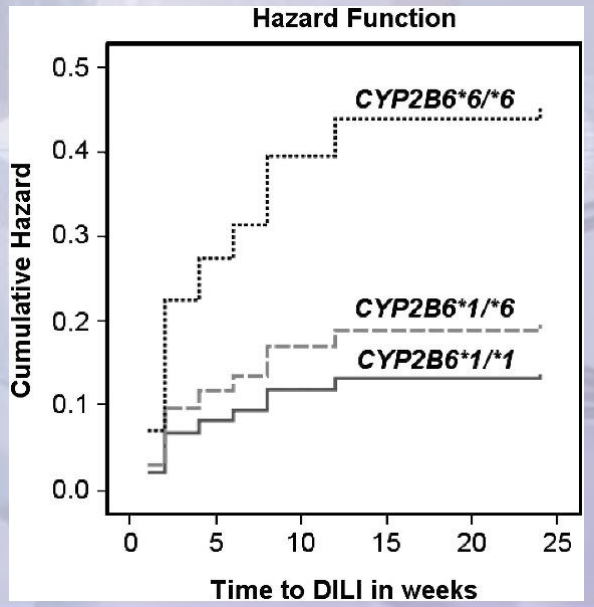
CYP2B6 polymorphisms common in African populations associated with increased efavirenz concentrations & adverse events

- Efavirenz is a potent inhibitor of HIV-1 replication with relatively narrow therapeutic index
- CYP2B6 is responsible for its metabolism (with minor contribution from CYP3A, 1A2, 2A6)
- Allele frequencies of CYP2B6 polymorphisms vary across racial groups
- Decreased activity of CYP2B6 is associated with higher efavirenz concentration and increased risks of adverse events (CNS side effects, DILI, etc.)

CYP2B6 allele frequencies across populations



DILI incidence vs CYP2B6 polymorphism



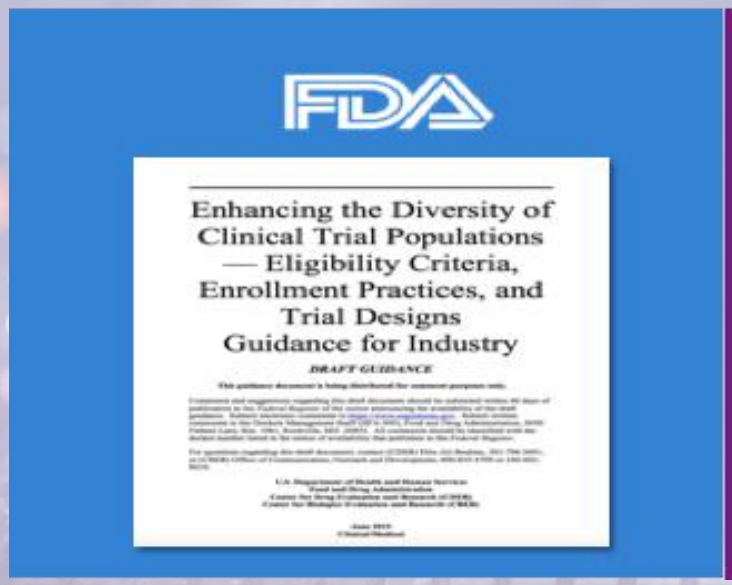
Zhou et al, Clin Pharmacol Ther. 2017 Oct;102(4):688-700. doi: 10.1002/cpt.690
Desta et al, Clin Pharmacol Ther. 2019 Oct;106(4):726-733. doi: 10.1002/cpt.1477.
Timer et al, Pharmacogenomics J. 2012 Dec;12(6):499-506. doi: 10.1038/tpj.2011.34.

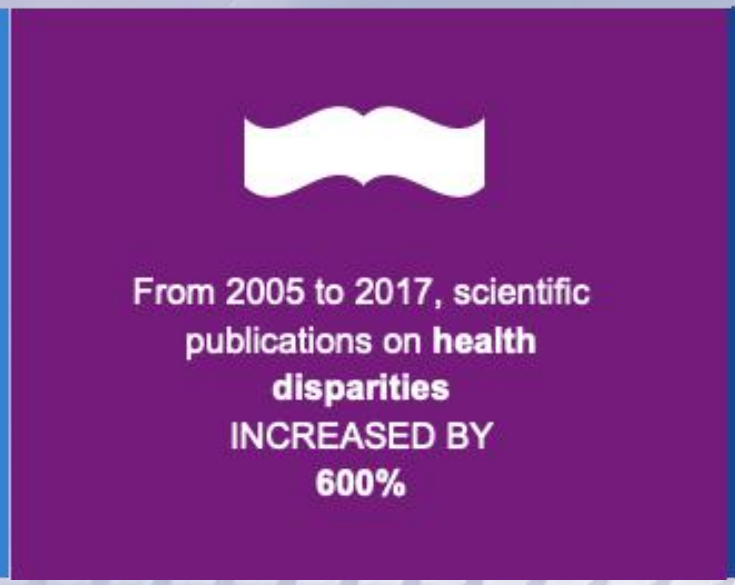
WHY DO INCLUSIVE SCIENTIFIC RESEARCH?

External Drivers Demanding Change

- **Population shifts and changing burden of disease**
- **Regulatory awareness**
- **Move towards personalized healthcare**
- **External spotlight on disparities with COVID-19**
- **Value-based healthcare and sustainability focus**
- **New standard expectation in science**

External Drivers Demanding Change





- COVID-19, Racial Social Justice and Media driving awareness and action in US and Globally
- Cancer Clinical Trial Eligibility Criteria: HIV, HBV, HCV: Guidance for Industry: July 2020
- Cancer Disparities and Health Equity: A Policy Statement From ASCO: August 2020
- The MRCT Center releases the Diversity, Inclusion, and Equity in Clinical Research Guidance, Toolkit and Website: August 2020
- IFPMA and PhRMA Diversity Workstreams: Developing Policy Statements/ Principles

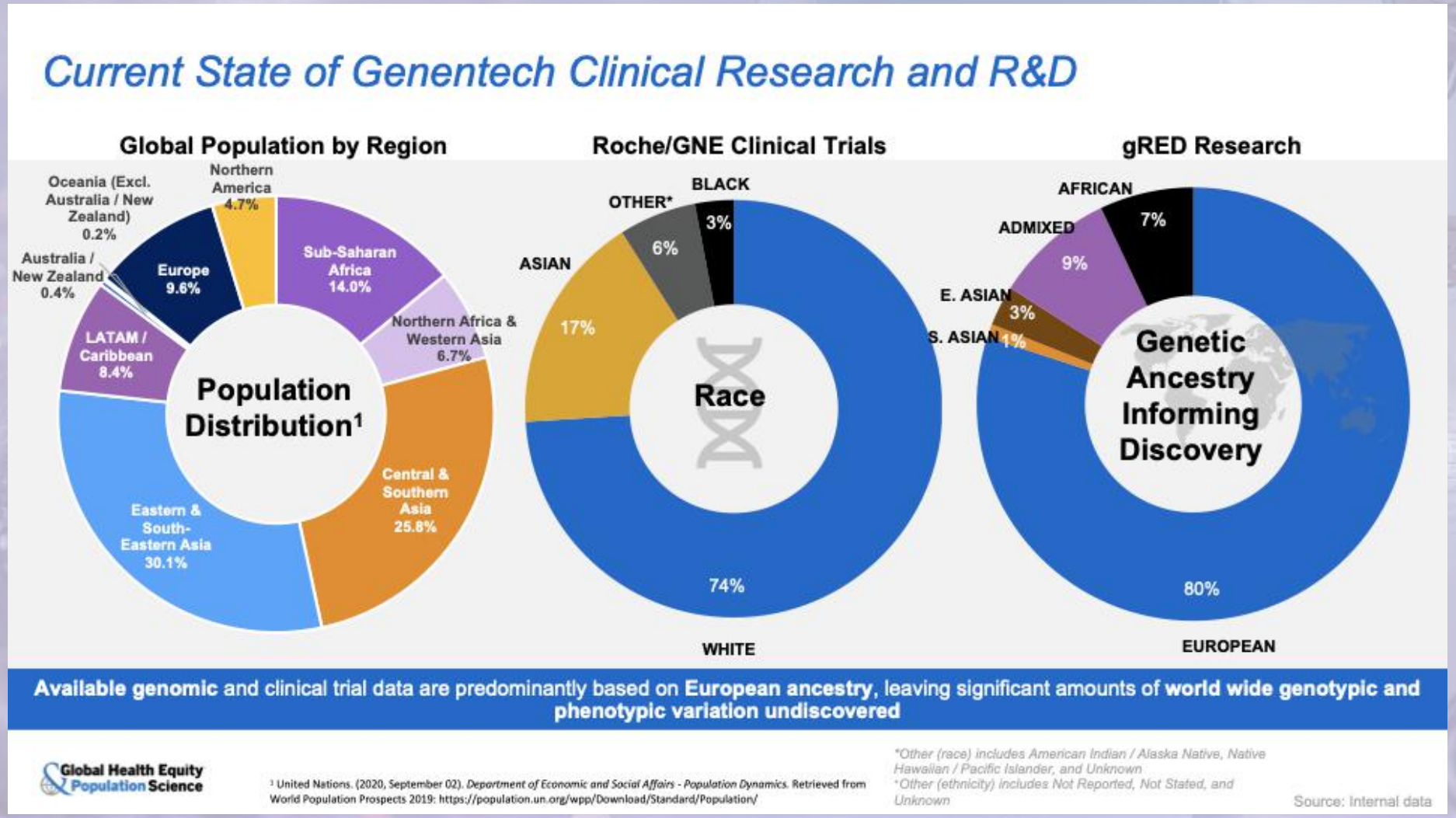
Content Courtesy of Global Health Equity and Population Science

FDA Draft Guidance: Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials (April 2022)

- Proposes the creation of a Race and Ethnicity Diversity Plan (recommends that sponsors also seek diversity in other areas e.g. sex, age, pregnancy, etc. but focuses on race)
- Applies to all drugs being developed and also includes devices
- Sets expectation that sponsors submit the plan no later than EOP2

Plan Component	Recommended Scope
Overview of Disease/Condition	Available data on pathophysiology of disease, disparity in treatment/outcomes
Scope of Medical Product Development	CDP, study design, study pop, known differences in PK/PD/PGx
Enrollment Goals	Based on disease epidemiology and/or existing knowledge of disparities
Plan of Action to Enroll/Retain	Detailed operational plans (e.g. sites, access, community, reduced burden)
Status of Meeting Goals	Performance vs. Expectations, with plan for post-marketing if necessary

Current State of Genentech Clinical R&D

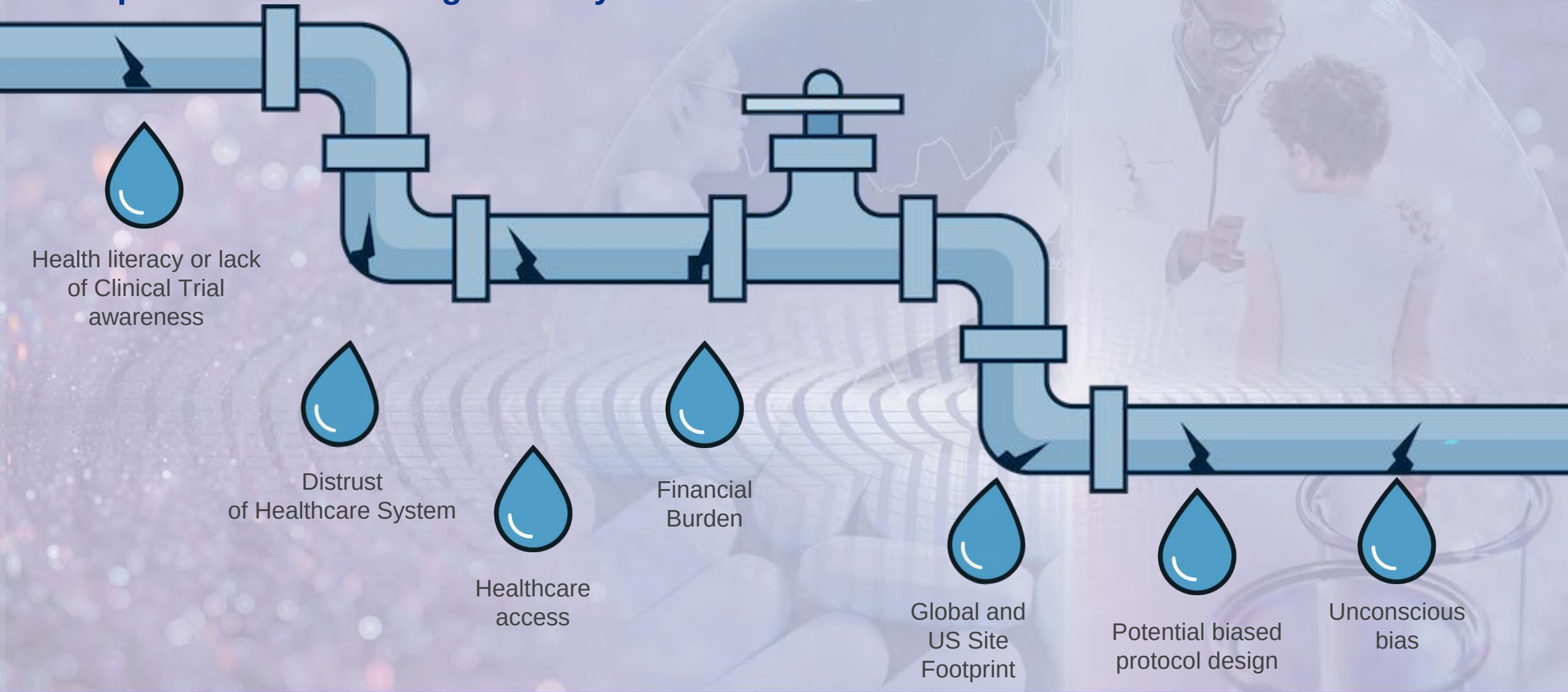


Thanks to ECDi gPA

Why Clinical Pharmacology?

- Many functional areas of expertise are relevant to address inclusive research
- Clinical Pharmacology is uniquely positioned to advocate for the importance of inclusive research
  - Interface with academic and developmental research, early and late stage clinical development, and post marketing teams
  - Existing knowledge base of impact of clinically relevant differences resulting from CYP450 enzyme polymorphisms and other changes
  - Expectation to assess impact of race on exposure

Complexities in achieving diversity in clinical trials in the US



Potential Solutions

- Raise awareness
- Educational outreach
- Site selection strategy
- Community engagement
- Less frequent clinical visits
- Partnerships

Summary

- Genetech/Roche recognizes the importance of inclusive research
- Status quo is not acceptable – we need to improve
- Clinical Pharmacology is uniquely positioned to advocate for inclusive research throughout drug development process
- There are significant challenges and hurdles that must be addressed
- Our patients are counting on us!

Potential CE Questions

- Challenges to the conduct of inclusive research include:
  - A) Cost
  - B) Lack of Trust
  - C) Lack of Access
  - D) All of the Above

- Clinical Pharmacologists are uniquely positioned to advocate for inclusive research because
  - A) They evaluate PK
  - B) They are from a quantitative discipline
  - C) They have historical experience and interact with many relevant drug development stakeholders
  - D) They are known for innovation

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  - D) They are known for innovation

The Importance of Outreach to Underserved Communities: Lessons from a Public Health Strategist and Patient Advocate

Jennifer Fields, MPH

President

The Hills Tandem, LLC

Strategy, Planning, and Management for Social Good…

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Financial Disclosures

- THT is a contracted consulting company with Graphite Bio.

Limited Resources For Outreach

Common Trends

Resources are plentiful for scientific research from pre-clinical to FDA approval

- Understand everything about the biological work of potential therapies
- Understand biology of the target population and how this can potentially impact biomarkers

Resources are few for community outreach at all phases of study

- Little to no resources on understanding the behaviors of the target populations based on culture
- Little to no resources spent on inclusion of the target population in participating in study phases
- Little to no resources developing programs that would support strong outreach at phase 1 onward

Result: Phase 3, we discover that the clinical trial has not met FDAs diversity and inclusion guidance recommendations

One Simple Clinical Question

Our Traditional Models of Care

The Four Models:

1. Paternalism: HCP makes an informed decision based on his own know knowledge.

2. Informative: HCP provides patient with all relevant information, patient to select the medical interventions he or she wants, physician to execute the selected interventions.

3. Interpretive: interpretive physician provides patient with information on condition, risks and benefits of possible interventions. Physician assists patients in articulating his or her values and in determining best interventions according to patient values. According to the interpretive model, the patient's values are not necessarily fixed and known to the patient.

4. Deliberative: HCP acts as a teacher or friend, engaging patient in dialogue on what course of action would be best. Not only does the physician indicate what the patient could do, but, knowing the patient and wishing what is best, the physician indicates what the patient should do, what decision regarding medical therapy would be admirable.

Has paternalism as a dominant model of care also become the mainstay model of care for all clinical research?

Community Question

ement

Have we used resources to ask the diverse community what is needed?

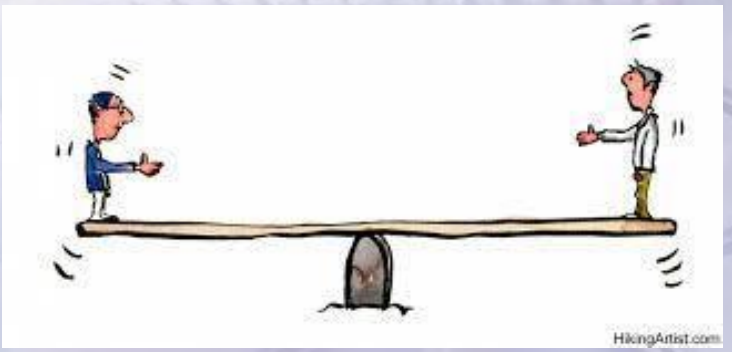
- A part of each research initiative should always include culturally appropriate social science activities
  - Ex. Design of educational materials – (mediums of information, photos, choice of words)
  - Ex. AA. Lay out all facts – Let them make the choice
  - Ex. African – Sometimes woman do not have a voice
  - Ex. Hispanic Families – Family decision

- Translating to community mean:

  Simply asking what is needed + Sharing the scientific need

  =

  Meeting in the middle



Variable Decisions Models Required

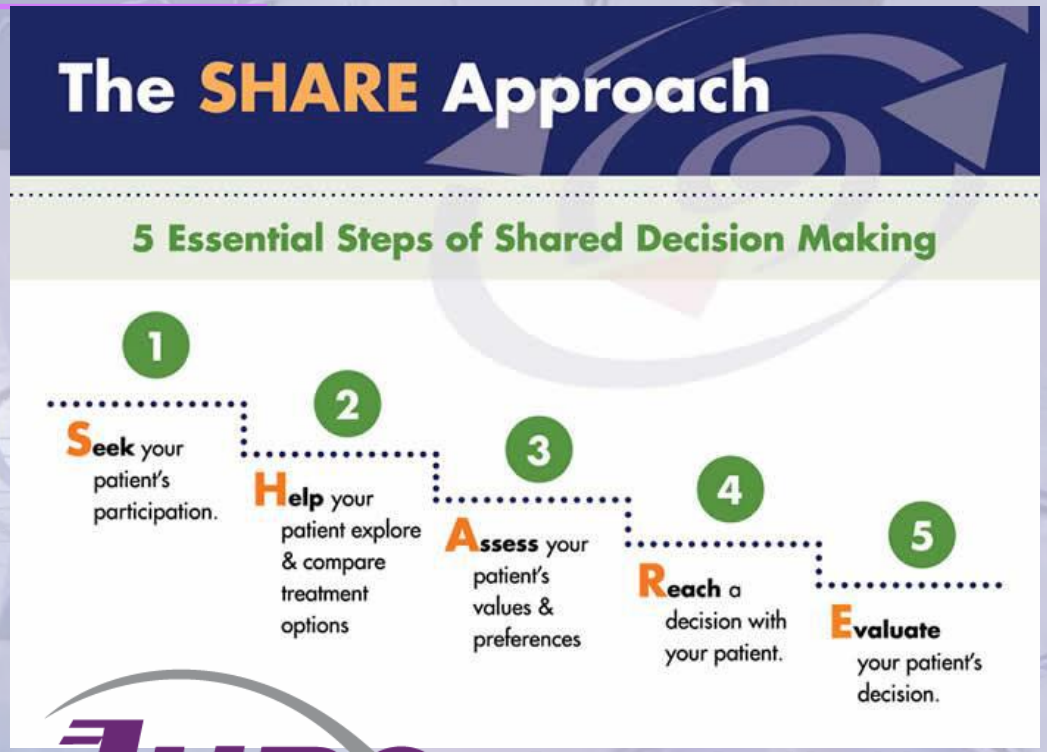
Patient & Community Perspective

- Is this tool utilized in healthcare or clinical research consistently or effectively?

- Understanding each culture means adjusting the decision models accordingly

  - Cultures makes decisions at various points on the models.
  - Decision points will be variable

- Was this made valuable enough for participation and disrupting every day norms?



AHRQ Agency for Healthcare Research and Quality

Solutions

Robust Partnerships

Without the patients, there would be no research. No research careers. No new discoveries. No exciting advancements in science.

ALL stakeholders SHOULD REDESIGN the meaning of EQUAL PARTNERSHIP in patient care and research.

Stakeholders
- Patients
- HCPs
- Researchers
- Families
- Payors
- Community Supports
- Clinical Pharmacologists

Solutions

Partnership Example: NCSCC

12 Certified Clinics in Sites of Greatest Need

Trained Personnel 2022

Physicians	21
Nurse Practitioners	4
Physician Assistants	3
Care Coordinators	24
Community Heath Workers	18

Solutions

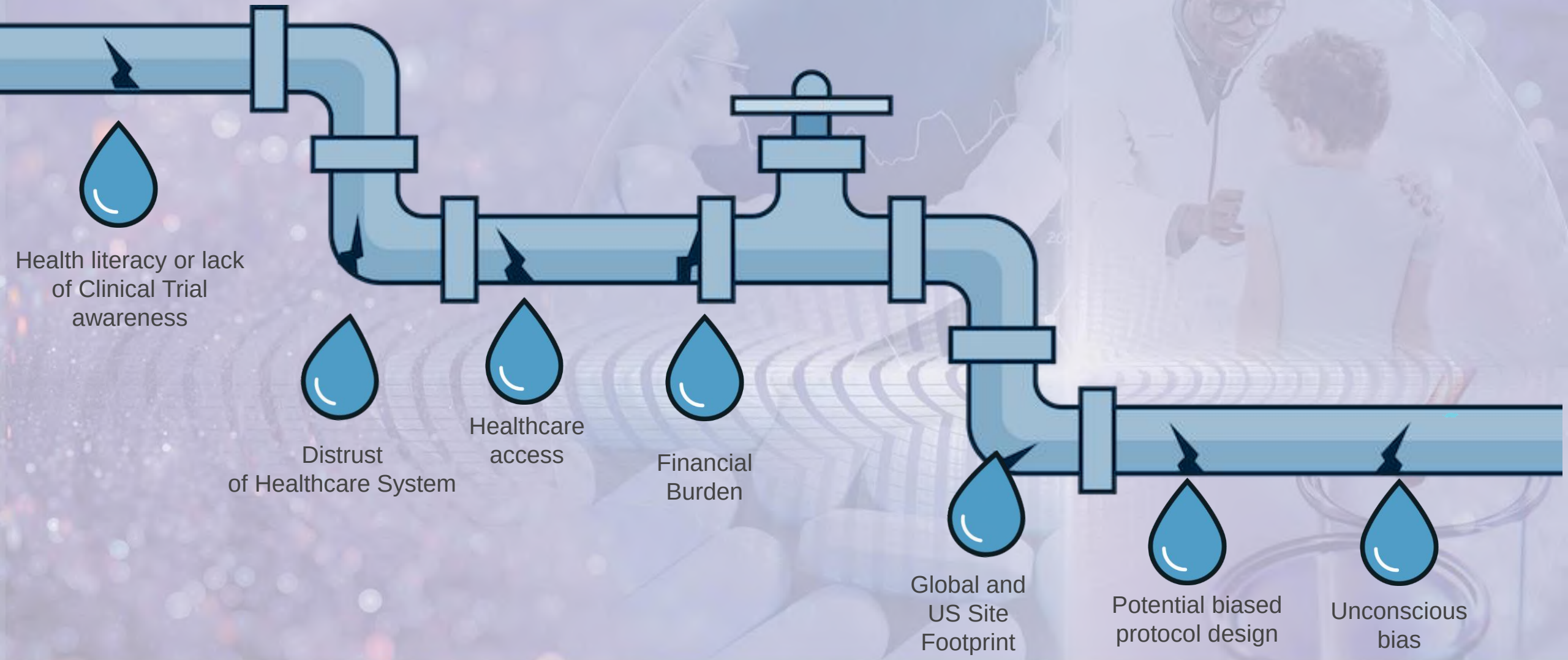
Community & Patient Led & Designed Outreach Initiatives

ALL stakeholders SHOULD REDESIGN the meaning of EQUAL PARTNERSHIP in patient care and research and allow the community to be fully respected – Include Culturally Developed and Sensitive Teams

Partner and trust the community to do their job

- Raise awareness
- Educational outreach
- Site selection strategy
- Community engagement
- Less frequent clinical visits
- Partnerships

Complexities in achieving diversity in clinical trials in the US



Why Outreach is Important in Underserved Communities

A Community Perspective

When everyone feels important in the process, trust is formed, relationships are born and participation increases.

When participation increases, we are able to find therapies and solutions to heal many.

The only issue with research diversity is a human connection issue.

We just need to feel like people not research subjects…

Thank You For Listening!

A community Perspective

PRESENTATION PREPARED BY:

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THE HILLS TANDEM

STRATEGY, PLANNING, AND MANAGEMENT FOR SOCIAL GOOD

DEI SYMPOSIUM
CASE STUDIES

Natella Rakhmanina, MD, PhD, FAAP, FCP, AAHIVS
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The George Washington University
Director, HIV Services & Special Immunology
Children's National Hospital
Senior Technical Advisor
Elizabeth Glaser Pediatric AIDS Foundation

ACCP
American College of Clinical Pharmacology®
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2022 ACCP Annual Meeting
Transforming Global Health through Clinical Pharmacology

Equity and Diversity in Clinical Trials Case Studies

- Case I – industry funded clinical trial on HIV prevention
- Case II – federally funded academic initiative to diversify clinical trials
- Key Strategic Points to take forward

CASE I - Novel Agent for HIV Pre-exposure Prophylaxis (PrEP)

- Black and Hispanic/Latinx cisgender men who have sex with men (MSM) and transgender women individuals have high burden of HIV infection
- They have been historically underrepresented in HIV PrEP clinical trials because of:
  - ✓*Underrepresentation of these communities in clinical research*
  - ✓*Stigma and* discrimination
  - ✓*Transphobia in research and medical settings*
  - ✓*Mistrust*

Cespedes M, et al. PLoS One. 2022 Jun 3;17(6):e0267780.

CASE I –PURPOSE2 Study Design

- **Purpose 2** (GS-US-528-9023; NCT04925752; sponsored by Gilead) - an ongoing Phase 3 clinical trial evaluating the safety and efficacy of lenacapavir (LEN) as PrEP for preventing HIV-1 infection in cisgender MSM and transgender people
- LEN is a first-in class capsid inhibitor administered subcutaneously (SQ) every six months
- In PURPOSE 2, participants are randomized in a 2:1 ratio to receive SQ LEN every 26 weeks plus daily oral placebo or daily oral emtricitabine/tenofovir disoproxil fumarate plus a placebo subcutaneous injection every 26 weeks
- The trial started in June 2021 with study sites in Brazil, Peru, South Africa, and the US, and will enroll approximately 3,000 individuals

Cespedes M, et al. PLoS One. 2022 Jun 3;17(6):e0267780.

When designing and planning this clinical trial, what would be your strategies to assure equity and diversity?

Strategies to Achieve Equity for Target Populations

- Engagement with community and patient stakeholders in the US and globally prior to protocol development - community forums, roundtable discussions, and individual meetings to understand community preferences, concerns, and challenges
- Input from these meetings incorporated along with recommendations from the literature
- The **Global Community Advisory and Accountability Group (GCAG)** was established to provide ongoing community engagement, assure accountability, and to serve as a resource to the study team and site investigators and staff
- In collaboration with 18 GCAG members, criteria for site selection and demographic inclusion goals were set
- Mandatory trainings was required for all individuals involved in the study
  - ✓*Good Participatory Practice (GPP) guidelines, which provides a framework for building effective partnerships with key stakeholders in research, gender inclusivity and antiracism*

Cespedes M, et al. PLoS One. 2022 Jun 3;17(6):e0267780.

CASE I - Novel Agent for HIV Pre-exposure Prophylaxis (PrEP)

- The trial target populations have shifted to include not only Black and Hispanic/Latinx cisgender men who have sex with men (MSM) and transgender women, but also ***transgender men, and gender nonbinary (TGNB)*** individuals have high burden of HIV infections

Cespedes M, et al. PLoS One. 2022 Jun 3;17(6):e0267780.

Effective Study Protocol Strategies

- Individuals selected to join the GCAG reflected the priority recruitment race, ethnic, and gender demographic goals of the study as well as the geography of the trial sites
- GCAG members were involved in each step of the study, including protocol development, site selection, development of participant-facing materials, and study implementation
- Examples of GCAG informed materials include:

✓TGNB-inclusive recruitment materials

✓Gender identity screening and organ inventory

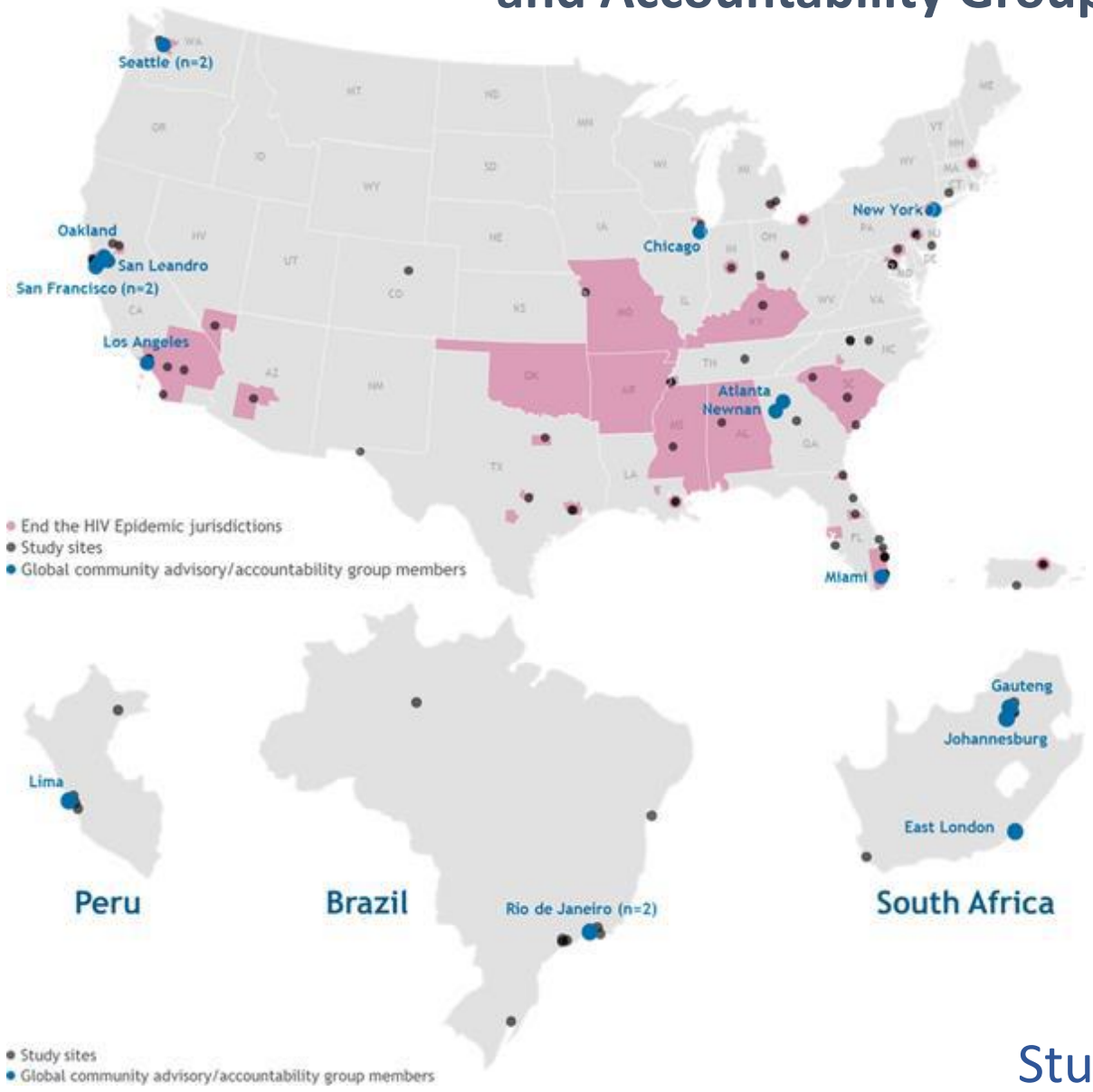
✓Inclusive, trauma informed sexual history taking guidelines;

✓Assessment of intimate partner violence and substance use and referral to appropriate support services

✓More accurately describing TGNB participant inclusion and exclusion criteria

Cespedes M, et al. PLoS One. 2022 Jun 3;17(6):e0267780.

PURPOSE 2 clinical trial study sites and locations of Global Community Advisory and Accountability Group (GCAG) members.



Factors in the selection of study sites:

- ✓ their prior work with individuals from diverse racial, ethnic and gender backgrounds
- ✓ local estimates of HIV incidence (using novel counterfactual study design comparing HIV incidence among participants on the study drug with the background HIV incidence)
- ✓ geographic regions that were the most disproportionately affected by HIV

Study website: http://www. purposestudies.com

Case I - Lessons Learned

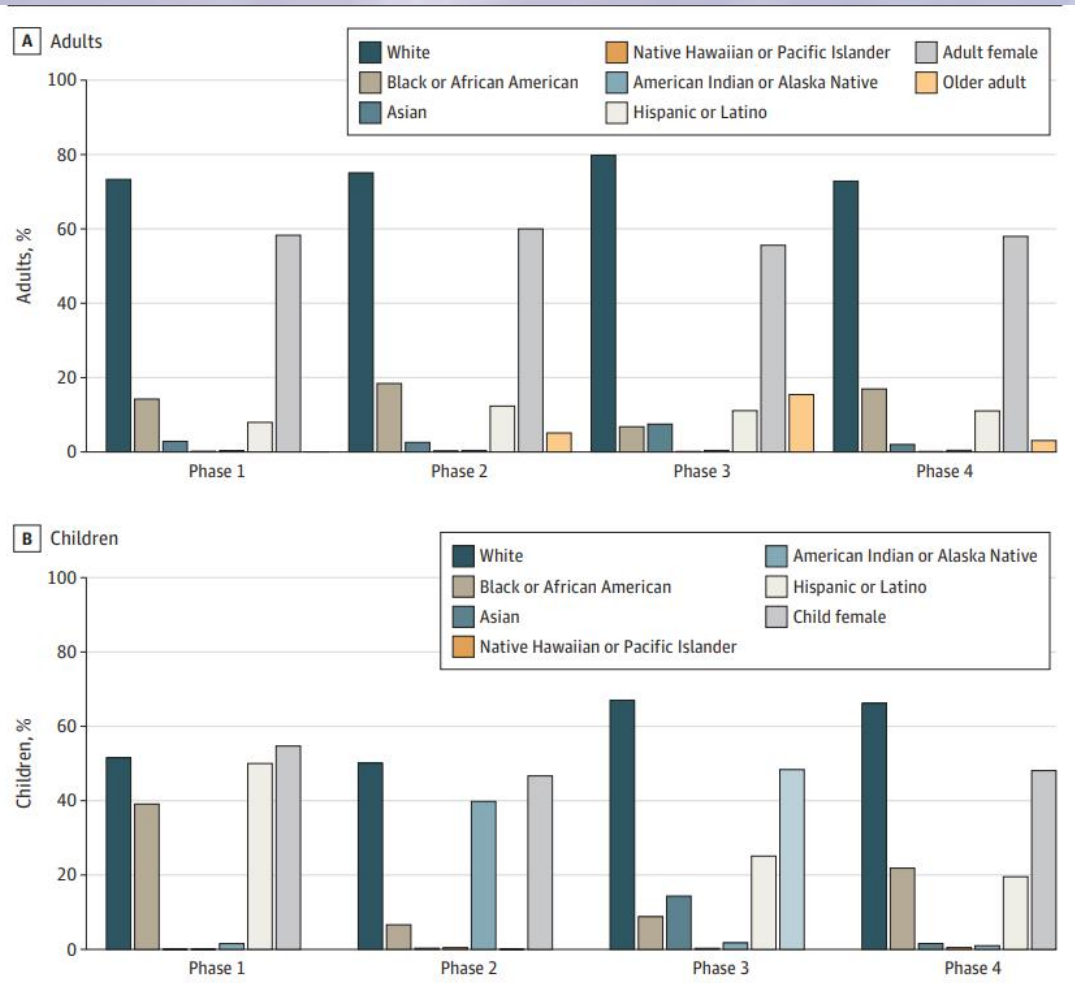
- Engaged with the community locally and globally in a sustainable manner
- Promoted culturally competent communication and transparency
- Broadened enrollment criteria to assure equity and diversity
- Built trust within the communities by selecting the most affected areas for the sites and engaging with experienced and sensitized staff
- Increased competency of study staff to address equity and diversity in a culturally-sensitive way
  Adapted study materials for the target populations

FDA Draft Guidance: Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials (April 2022)

Plan Component	Recommended Scope
Overview of Disease/Condition	Available data on pathophysiology of disease, disparity in treatment/outcomes
Scope of Medical Product Development	CDP, study design, study pop, known differences in PK/PD/PGx
Enrollment Goals	Based on disease epidemiology and/or existing knowledge of disparities
Plan of Action to Enroll/Retain	Detailed operational plans (e.g. sites, access, community, reduced burden)
Status of Meeting Goals	Performance vs. Expectations, with plan for post-marketing if necessary

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations

We Need Diversified Outreach Strategies for Diverse Populations



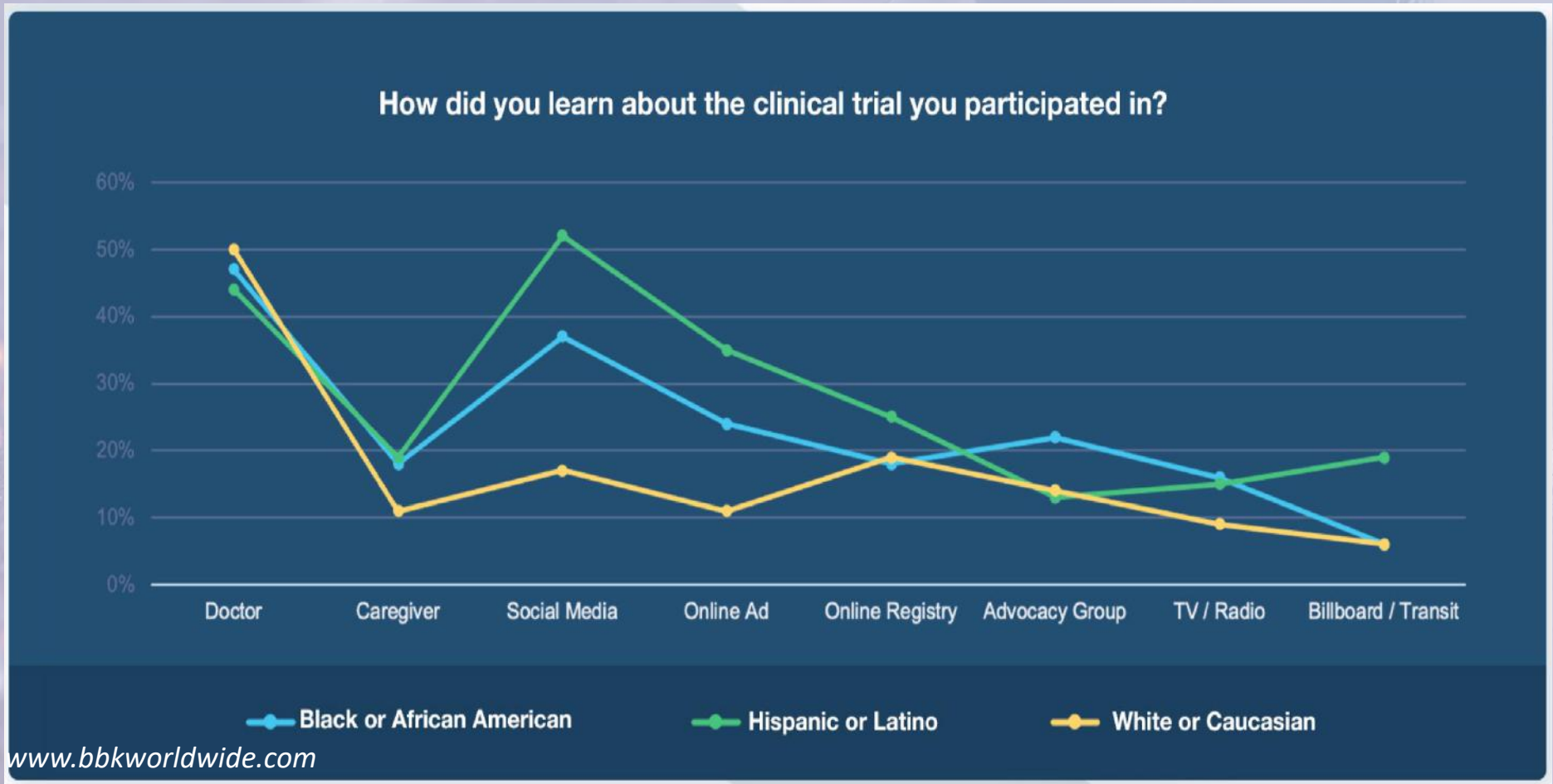
A, Percentages for older adults were calculated among all trials reporting age as a percentage.

Inclusion of Racial/Ethnic Minority, Female, and Older Individuals in Vaccine Clinical Trials In the USA

- ✓ Adult participants from minority groups were underrepresented
- ✓ Large percentage of trials had no data available on minority groups, particularly Hispanic and Latino populations
- ✓ Missing data may be important in the context of understanding health disparities, such as social determinants of health (e.g., socioeconomic barriers), implicit bias, and an increased burden of comorbidities.
- ✓ Combined with studies that document lower vaccination rates and increased disease burdens in some of these populations, these data highlight the need to improve minority group enrollment in clinical trials.

Flores LE, et al. JAMA Network Open 4, no. 2 (2021)

Diversified Outreach Strategy Needs



www.bbkworldwide.com

Voice Study

- USA Healthcare consumers survey in August 2021
- 2,078 adult participants
- 74% would consider participating in clinical trial
- 13% participated in clinical trial previously
- 47% highly motivated by reimbursement
- 68% ranked in-person visit above telemedicine

Social Media appears to be a more effective outreach tool for the Hispanic/Latino and Black/African American populations

CASE II - Yale Center for Clinical Investigation (YCCI)

- In 2006 with a support from an NIH grant YCCI was created at Yale School of Medicine, New Haven, Connecticut, to support the growth of clinical trials
- New Haven's population, which is 34% Black or African American and 31% Hispanic or Latino.
- ***Diversification of clinical trails became a key objective***
- Key elements of the YCCI:

✓*Cultural Ambassador Programs intended to foster a partnership with community leaders, and investigator teams (established in 2010)*

✓*Leveraging patient portal in research by developing innovative ways of utilizing Electronic Health Records (EHRs) to house research activities*

✓*Incorporating clinical research recruitment call centers with extended hours to accommodate patients interested in research outside of business hours*

https://medicine.yale.edu/ycci/

How would you approach building stronger community liaison/engagement program to support clinical trial?

CASE II – YCCI Cultural Ambassador Program

- Partnerships with the Connecticut African Methodist Episcopal Zion Churches (AME Zion), one of the oldest African American Congregations in the US, and with Junta, one of the first Latinx local community-based non-profit organization
- Connecticut AME Zion and Junta partners select the Cultural Ambassadors who provide bidirectional collaboration
- Ambassadors receive ~200 hours in research training to assist in research operations and provide feedback on community needs, ideas, and interest

https://medicine.yale.edu/ycci/

CASE II – YCCI Cultural Ambassador Program

Cultural Ambassadors:

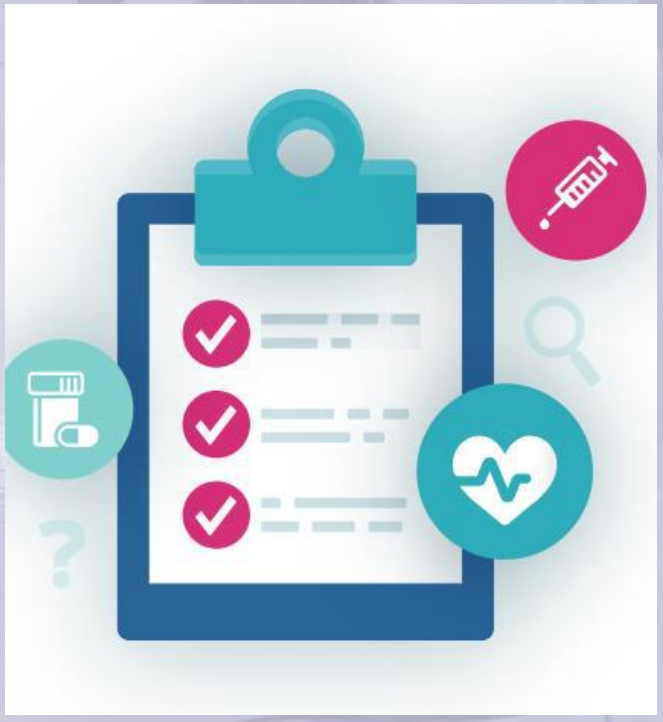
- ✓ *Host activities in the community to raise awareness about ongoing research*
- ✓ *Assist in and provide input on recruitment campaigns plans*
- ✓ *Assess protocols during the design phase*
- ✓ *Translate the study material and informed consent forms*
- ✓ *Participate in monthly community grand rounds*

- ➢ ***In 2018, Yale, Community partners and the FDA Office of Minority Health and Health Equity have partnered to catalyze racial equity in clinical trials through community empowerment***

https://medicine.yale.edu/ycci/

CASE II - Cultural Ambassador Programs at YCCI

- "Help Us Discover" volunteer profile was converted from paper to an electronic profile and made available through a Yale research tab in MyChart patient portal
- Without any direct advertisements at first, the MyChart research profiles resulted in >3,329 new volunteers for clinical trials, with 2,603 subjects referred to and screened for a study
- YCCI rolled out new direct to patient recruitment functionality through MyChart which allows the EHR to automate high level matching of patients based on study inclusion/exclusion criteria and sends alerts directly to the patient's MyChart



https://medicine.yale.edu/ycci/

Case II - Lessons Learned

- YCCI assured consistent and continued community engagement:

✓Total underrepresented minorities participation in all clinical trials has increased from 2% to >30%

✓Each study that engaged with the Cultural Ambassadors had improvements in participation of underrepresented groups, ranging from 22% - 91%, with one exception at 12% underrepresented participation

✓"Help Us Discover" volunteer and recruitment platform has been used in 40 studies with underrepresented minorities who were screened and recruited making up 35% of the interested respondents

✓57% of the underrepresented minority respondents came after business hours or on weekends, suggesting that digital outreach may enhance underrepresented recruitment by being available 24 hours a day

-

https://medicine.yale.edu/ycci/

Key Strategies Making Diversity a Focus for Clinical Trial

- Actively promote diversity and include site level diversity plans
  - ✓ *account for the site, region and overall trial level diversity*
  - ✓ *include input from different demographics and local communities*
  - ✓ *develop appropriate educational and promotional materials in line with the diversity plan*
- Include community outreach programs to educate and identify potential clinical trial participants
  - ✓ *build strong relationships with communities for engagement and gaining trust*
  - ✓ *gain deep understanding of people's views within communities, local to clinical trial sites*
  - ✓ *create tailor-made outreach programs - working with patient groups, community organizations, religious groups, local businesses or places of leisure by offering education, knowledge and the opportunity to become involved*

www.innovativetrials.com/diversity

Key Strategies Making Diversity a Focus for Clinical Trial

- Include targets for each population in the protocol and recruitment plan
- Optimize patient referrals to expand into target demographics
  - ✓ *support patients to talk to others, and have materials to help them explain the trial within their communities*
- Make the reporting and publishing and dissemination of diversity statistics a requirement

www.innovativetrials.com/diversity

Key Strategies Making Diversity a Focus for Clinical Trial

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ACCP Voice: Importance of Diversity and Inclusion in Drug Development and Clinical Trial Conduct

ACCP strongly recommends that researchers and healthcare professionals across the care continuum be more active regarding the need for greater diversity of participants in drug development and clinical trials by:

- Actively participating in the professional and academic institutions, societies, and local communities
- Strongly considering actions of advocacy, mentoring, education and volunteering to better inform all stakeholders regarding the need for greater diversity of participants in clinical trials and the drug development process
- Striving to ensure our actions in the design, conduct, reporting and communication of clinical research reflect the diverse needs of our communities

Moore KT, et al. J Clin Pharmacol. 2022 Sep 8. Epub ahead of print.

ACCP Voice: Importance of Diversity and Inclusion in Drug Development and Clinical Trial Conduct

Potential Strategies to Remove Existing Barriers in Clinical Trial Diversity

1. ***Enhance healthcare practitioner training in clinical research, bioethics, and best practices while also involving more community health professionals in the clinical trial process:***

- ✓ enlist more community-based healthcare professionals into research
- ✓ extend the overall reach, reduce recruitment delays, and enroll a trial population that better resembles the eventual users of the product
- ✓ enhance local healthcare practitioner education and training
- ✓ strengthen community partnerships in a transparent, effective and culturally appropriate manner
- ✓ foster the development of an ethnically diverse research team
- ✓ improve communication and rebuild trust in the communities that are likely the most impacted by the disease states being researched
- ✓ establish greater understanding and communication around medicine and clinical research within our communities

Moore KT, et al. J Clin Pharmacol. 2022 Sep 8. Epub ahead of print.

ACCP Voice: Importance of Diversity and Inclusion in Drug Development and Clinical Trial Conduct

Potential Strategies to Remove Existing Barriers in Clinical Trial Diversity

2. Embrace novel clinical trial design and improving trial conduct:

- ✓ consider novel trial designs and improve how trials are conducted
- ✓ use designs that are more patient-centric such as adaptive and decentralized trial designs
- ✓ incorporate clinical pharmacology modelling
- ✓ use real-world evidence to better inform and enhance drug development
- ✓ Use new technological modalities to improve data collection and monitoring such as remote data capture through wearable technology, virtual clinic appointments, telehealth, digital health technologies, mobile sample collection (when possible), and home health visits
- ✓ address ethically sound compensation practices

Moore KT, et al. J Clin Pharmacol. 2022 Sep 8. Epub ahead of print.

ACCP Voice: Importance of Diversity and Inclusion in Drug Development and Clinical Trial Conduct

Potential Strategies to Remove Existing Barriers in Clinical Trial Diversity

3. Greater involvement and role of Institutional Review Boards and Research Ethics Committees to ensure trial diversity:

- ✓ advocate for IRB to have at least five members with varying backgrounds to assure diversity of the members, including consideration of race, gender, cultural backgrounds and sensitivity
- ✓ maximize the inclusion of understudied groups when consistent with the aims of the study
- ✓ assure greater IRB monitoring through the recruitment/enrollment period to ensure the population selected represents the demographics of the condition being studied
- ✓ use ad hoc consultants, patient care advocates and community representatives for representation that is reflective of the communities the research is being conducted in

Moore KT, et al. J Clin Pharmacol. 2022 Sep 8. Epub ahead of print.

ACCP Voice: Importance of Diversity and Inclusion in Drug Development and Clinical Trial Conduct

Potential Strategies to Remove Existing Barriers in Clinical Trial Diversity

4. Engagement with the community and patient advocacy:

- ✓ support adequate funding for patient advocacy programs and community initiatives
- ✓ assure involvement of healthcare professionals and researchers familiar with clinical research and drug development at every level of community participation
- ✓ actively participate in community events
- ✓ engage with local government officials, religious leaders, educators and neighbors, or mentoring local healthcare professionals in the fields of bioethics and medical research
- ✓ broaden the overall health literacy of the community and increase their involvement in every stage of clinical research

Moore KT, et al. J Clin Pharmacol. 2022 Sep 8. Epub ahead of print.

Please, stop at the ACCP IDE Committee Booth at the Poster Session!

Consider becoming an IDE Committee member and helping us shape the future of ACCP and clinical pharmacology!

How can CROs support increasing diversity in clinical trials?

Rodrigo Garcia, MD, MS
Vice President, Sites and Patients Center of Excellence
Operational Strategy Unit
September 2022

The world leader in serving science

Topics

1. Why CROs should consider diversity in clinical trials
2. What is the benefit for CROs?
3. How can CROs support diversity in clinical trials?
4. What PPD is doing

Why Should CROs consider supporting Diversity in Clinical Trials?

It's estimated that nearly **three out of every four clinical trials** today are conducted by contract research organizations (CROs)

- We can play a major role in generating more diverse representation in clinical trials

Many sponsors are initiating campaigns and allocating resources to combat barriers to underserved/ underrepresented patients

- We want sponsors to see us as a partner in this space not an additional barrier that they have to navigate

The FDA' most recent draft guidance about Diversity Plans will have an impact on overall study/molecule strategies that CROs execute

- We will need to carefully consider and adapt to diversity considerations when developing proposals

Rodrigo.garcia@ppd.com | September 2022

Clinical Trials Are Not Representative of Real-World Populations

Table 1. Percent Participation in Clinical Trials by Subpopulation* for New Molecular Entities and Therapeutic Biologics Approved in 2020

	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 AND OLDER	UNITED STATES
AVERAGE	56%	75%	8%	6%	11%	30%	54%

* The percentage of all other races combined (American Indian or Alaska Native, Native Hawaiian or other Pacific islander, Other, Unknown/Unreported) makes up to 100% of race category.
* The percentage of Non-Hispanic and Unknown/Unreported ethnicity makes up to 100% of ethnicity category.
* The percentage of patients from anywhere else in the world makes up to 100% of geographic category.

+ The US accounts for over 50% of trial participants globally, of which 75% identify as white/European descent.

+ Although Hispanic patients only account for 11% of clinical trial populations they currently represent 18.4% of the US population.
+ Asian Americans are the fastest-growing population in the US with 81% increase from 2010-2019.

	Estimate	Margin of Error	Percent	Percent Margin of Error
⌄ Total population	328,239,523	*****	328,239,523	(X)
› Hispanic or Latino (of any race)	60,481,746	±11,342	18.4%	±0.1
⌄ Not Hispanic or Latino	267,757,777	±11,342	81.6%	±0.1
White alone	196,789,401	±22,517	60.0%	±0.1
Black or African American alone	40,596,040	±70,047	12.4%	±0.1
American Indian and Alaska Nati...	2,236,348	±22,027	0.7%	±0.1
Asian alone	18,427,914	±39,236	5.6%	±0.1
Native Hawaiian and Other Pacifi...	565,473	±15,316	0.2%	±0.1
Some other race alone	839,270	±29,578	0.3%	±0.1

FDA drug trial snapshot 2020 https://www.fda.gov/media/145718/download
US Census American Survey Estimates 2019 https://data.census.gov/cedsci/profile?g=0100000US
https://www.pewresearch.org/fact-tank/2021/04/09/asian-americans-are-the-fastest-growing-racial-or-ethnic-group-in-the-u-s/

Global Populations are Changing in Size and Composition

Demographics are becoming gradually more heterogeneous.

Global populations are shifting due to increases of regional growth.

2027

India projected to replace China as world's most populous country

2045

US will be a Minority-Majority nation

2099

8/10 people will live in India or Africa

2060

30% of the UK population will be ethnic minorities

What is the Benefit for CROs?

It's the right thing to do	• Global health equity is goal we should all want to be apart of
CROs have an opportunity to play a lead role in advancing clinical trial diversity	• CROs are uniquely positioned to connect sponsors and site patient diversity efforts and champion this work in a way sponsors and sites cannot on their own
Improved partnerships with Sponsors and Sites	• Sponsors need support in diverse enrollment and broadened site selection and can see the CRO as a partner or a barrier • Sites need us to advocate on their behalf; we need to acknowledge the significant work burden they face
Upfront investment = Long Term Value Add	• Diversity in clinical trials isn't a fleeting trend; instead regulators are more consistent and insistent in requiring diverse patient representation


SITE
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HEY EVERYONE.
COVID'S
OVER SO THE
CLINICAL TRIAL
INDUSTRY CAN
GO BACK TO NORMAL


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ALL THE
NEW TECH
VENDORS FROM
SPONSOR/CRO

PHARMA

'In the long-term interests': FDA oncology chief defends rejection of Lilly, Innovent cancer drug

By **Angus Liu** • Mar 28, 2022 08:34am

U.S. FDA | Richard Pazdur | Eli Lilly | PD-1/L1

In an interview with Fierce Pharma, Pazdur, director of the FDA's Oncology Center of Excellence (OCE), defended the rejection.

"I am not against China, that was not the implication here," Pazdur said in an interview. "It was a future-directing approach to what drug development should be."

https://www.fiercepharma.com/pharma/its-long-term-interests-fda-oncology-chief-pazdur-defends-rejection-eli-lilly-innovents-pd-1

FDA rejects two China-developed cancer drugs

The regulator cited concerns around single-country trials in turning back Hutchmed's pancreatic cancer treatment, while manufacturing issues held up Junshi and Coherus' throat cancer medicine.

Published May 2, 2022

In the FDA's letter to Hutchmed, the regulator said additional trials would need to include patients more representative of people in the U.S. who have neuroendocrine tumors, as well as comparing surufatinib to the standard of care in the U.S.

https://www.biopharmadive.com/news/fda-reject-hutchmed-junshi-china-developed-cancer-drug/623024/

How Can CROs effectively support increasing Diversity in Clinical Trials “empower

Initial protocol assessment and budget considerations

- Proactively include patient centric offerings proactively
- Consider increase site budget to support additional efforts
- Stop fearing additional budget

Feasibility

- Ensure diversity/disparity epidemiology is considered
- Don’t be afraid of new sites
- Proactively communicate to sites the desire for greater diverse patient diversity

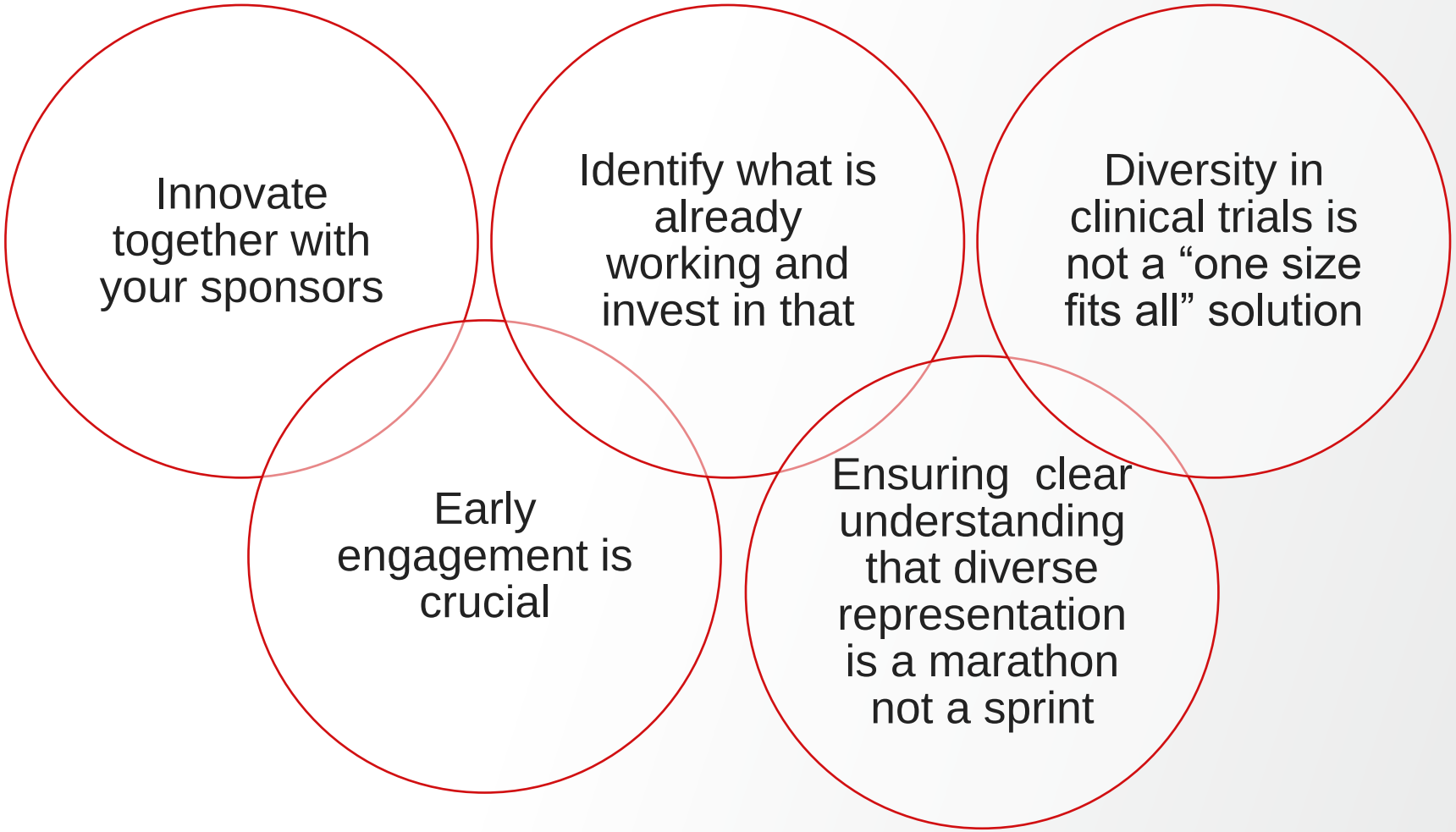
Site Support

- Hold study-agnostic site interviews
- Proactively communicate resource constraints
- Encourage monthly site payments

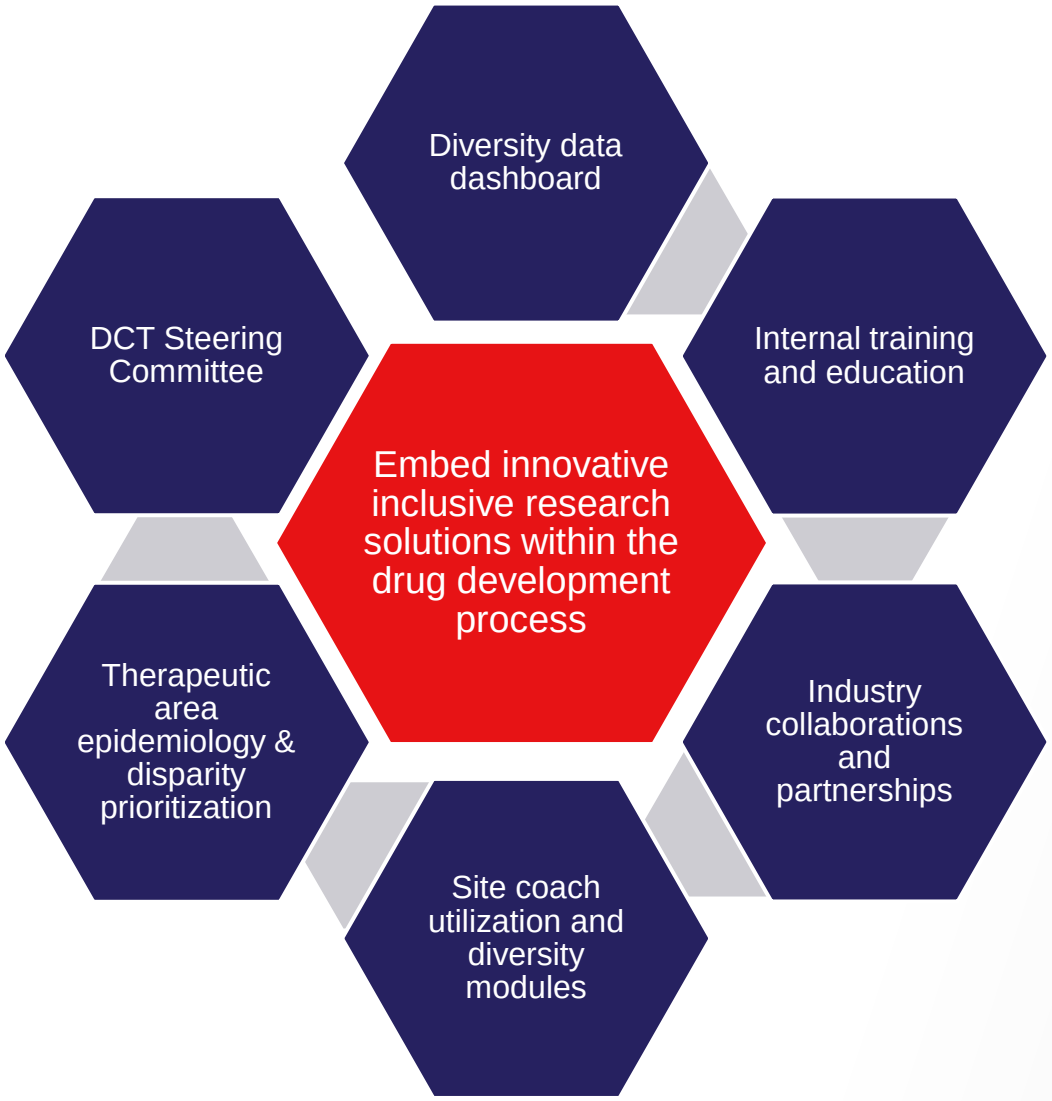
CRA/PM/CTM training

- Ensure comfort with talking about DEI
- Provide training of DiCT rationale
- Empower to advocate for their sites

How Can CROs effectively support increasing Diversity in Clinical Trials



What is PPD doing to support Patient Diversity?



Rodrigo.garcia@ppd.com | September 2022

Identified barriers to achieving proper diversity in clinical trials

Historic lack of trust and cultural competency	Unconscious biased towards patients and their willingness to participate in clinical trials
Limited health literacy and clinical trial awareness	Historic unethical clinical research practices
Limited access to clinical trials	Varying levels of understanding, ICF reading level too high
	Traditional sites lack proper training and experience recruiting minority patients
Overly restrictive eligibility criteria & complicated protocol design	Eligibility criteria inadvertently excluding minorities due to comorbidities & lab values ranges
Financial toxicity and burden in personal life	Distance to site, child/senior care, impact on work schedules, logistical cost

Key PPD innovative solutions to address diversity in clinical trials

- Targeted minority patient engagement plans
- Enhanced site & patient educational materials & decentralized trial tools
- PPD Digital, site coach, data driven feasibility and site placement
- Protocol optimization & broadened and inclusive study design recommendations
- Patient concierge, travel and transportation reimbursement

Rodrigo.garcia@ppd.com | September 2022

Thank You!

Diversityinclinicaltrials@ppd.com

The Need for greater DIVERSITY in Clinical Trials

Agenda

The concept of Diversity

Why Diversity in Clinical Trials is an enterprise priority

How Bristol Myers Squibb is addressing this important topic and Diversity Goals

A case study: prostate cancer in the Black American population

Understanding the Global Nature of Diversity





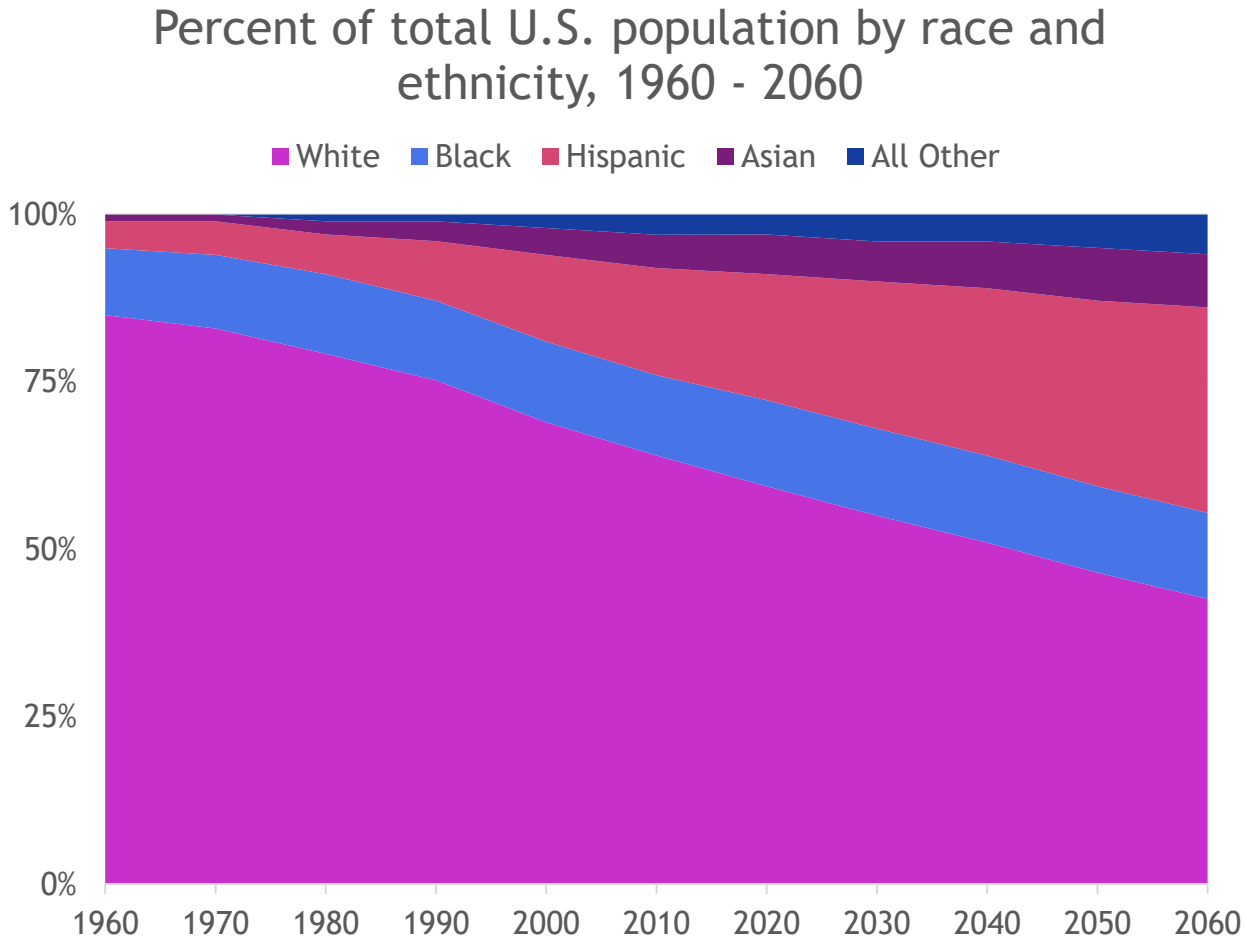





America’s racial and ethnic tapestry is changing

- **Race** is ascribed to individuals on the basis of physical traits while ethnicity is more frequently chosen by the individual

- **Ethnicity** encompasses everything from language, nationality, culture and religion, and can enable people to take on several identities

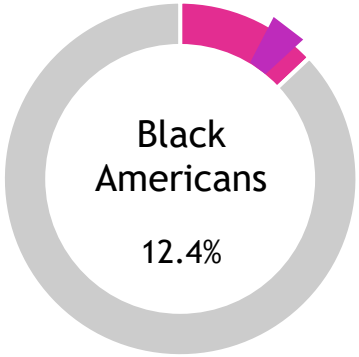


LifeScience Magazine, February 2020

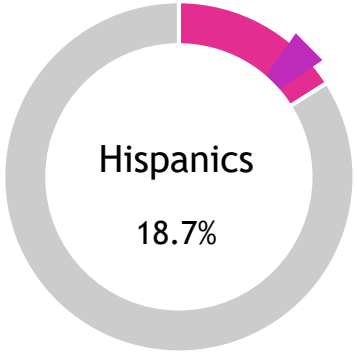
Source: The Next America, PEW Research, 2014 - updated

Impact of race and ethnicity on clinical trials

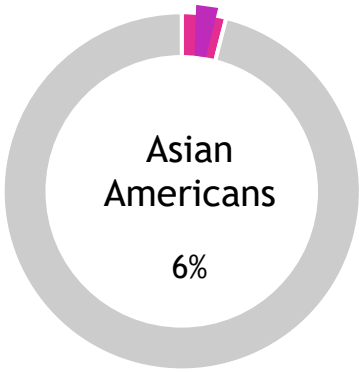
Clinical trials conducted today in the US lean heavily toward patient participant populations that are 80% white



Black Americans represent 12.4% of the US population but only ~4% participate in clinical trials



Hispanics represent 18.7% of the US population but only ~3% participate in clinical trials



Asian Americans represent 6% of the US population but only ~3% participate in clinical trials

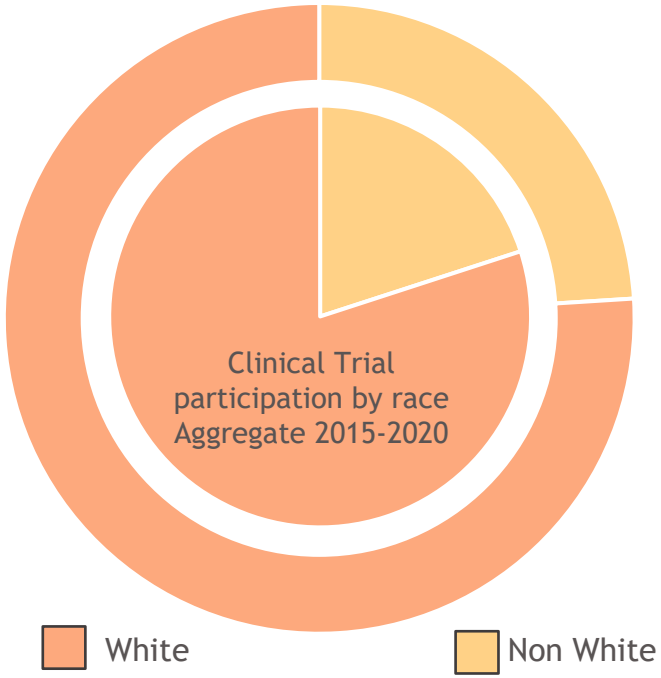
Total U.S. population % of race within U.S. population % participation of race in CT

(1) Race and Ethnicity in the United States: 2010 Census and 2020 Census data visualization - https://www.census.gov/library/visualizations/interactive/race-and-ethnicity-in-the-united-state-2010-and-2020-census.html
(2) Cancer Facts & Figures 2020 https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/annual-cancer-facts-and-figures/2020/cancer-facts-and-figures-2020.pdf
(3) The Burden of Cancer in Asian Americans: A Report of National Mortality Trends by Asian Ethnicity http://cebp.aacrjournals.org/content/25/10/1371

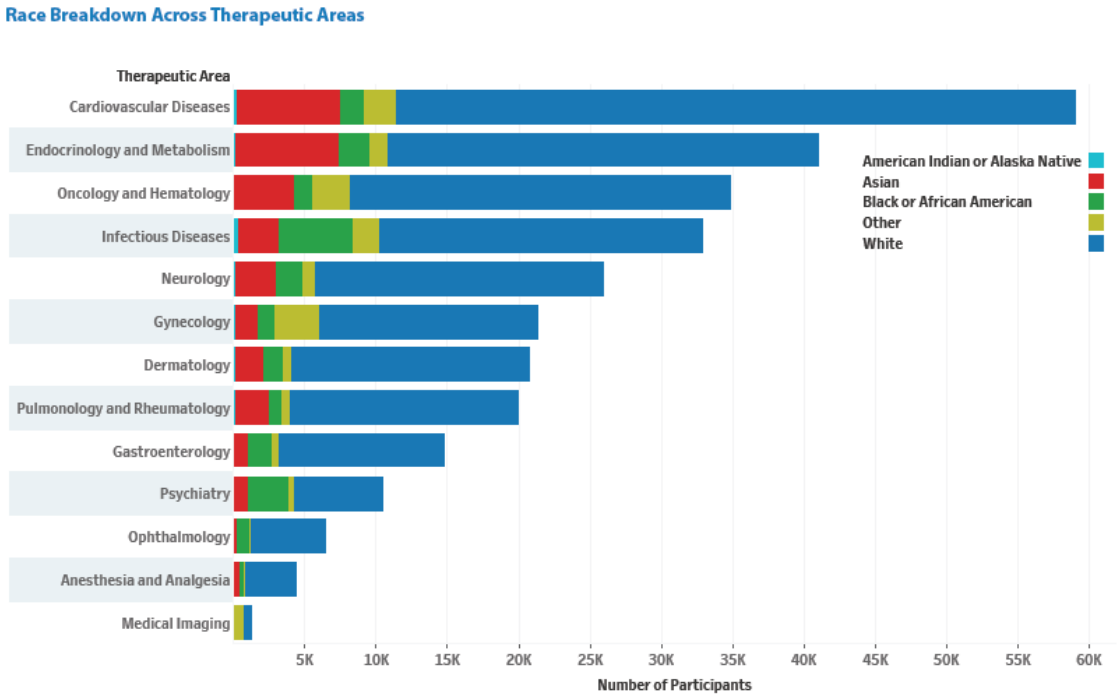
How can race and ethnicity impact clinical trials?

Clinical trials conducted today in the US lean heavily toward patient participant populations that are ~80% white

2019 US Census aggregate (race)



Race breakdown across Therapeutic Area(2)



Source: (1) 2019 Quick Facts US Census https://www.census.gov/quickfacts/fact/table/US#
(2) FDA Drug Trials Snapshots Summary Report 2015 - 2019

Potential Barriers to Clinical Trial Participation

Sponsors	• Variable understanding of what the patient needs to participate: impact to daily life • Limited interest in inexperienced sites and investigators • Lack of direct communication to sites about the need and importance of clinical trial diversity
Clinical trials research sites	• Lack of diverse investigators and research staff • Site start up costs are expensive • Lack of referral to trials (bias) or lack of community engagement • Inexperienced research sites that have ongoing research but may overlook a diverse population
Patients and caregivers	• Practical obstacles to participation: transportation, childcare, lack of insurance • Lack of trust in pharma and medical research • Low health literacy, not limited to language barriers • Lack of awareness of clinical trials • Lack of research savvy clinicians within healthcare facilities
Societal Factors	• Qualified subjects are not always offered the opportunity to participate • Socio-economic burdens to the participant can be overlooked: cost of transport, childcare, cost of missing work

Reasons for Industry Prioritization

Research suggesting certain subpopulations may respond differently to the same medication based on their age, gender, weight, **racial/ethnic identity**, etc.

- Higher incidence, prevalence and Mortality for Multiple Myeloma yet less benefit seen in novel therapies
  - 5-year survival rate increased 26.3%-35% White Americans while 31-34.1% for Black Americans[1]

Global Acceptance of DiCT as an important focus in data generation from reputable organizations

- International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)
- FDA Enhancing Diversity of Clinical Trial Populations & Diversity Plan Guidance
- ICH Guidance

Heightened Awareness of Global Health Inequity due to Covid-19 pandemic

Ensuring that there is scientific merit and patient trust in the drug development process

Commitment to developing treatments that are patient-focused and address the communities burdened by the disease

Source: (1) Recommendations on Eliminating Racial Disparities in Multiple Myeloma Therapies: A Step toward Achieving Equity in Healthcare
https://aacrjournals.org/bloodcancerdiscov/article/2/2/119/2099/Recommendations-on-Eliminating-Racial-Disparities

How is BMS addressing this important topic

Bristol Myers Squibb Diversity in Clinical Trials

Bristol Myers Squibb's mission is to transform patients' lives through science by **discovering**, **developing**, and **delivering** innovative medicines that help them prevail over serious diseases

BMS is **committed** to doing its part to help ensure patients have a fair and just opportunity to achieve optimal health outcomes.
BMS is working to improve the recruitment of a diverse participant population with the goal that the clinical trial becomes more **reflective of the real-world population** and the **people impacted** by the diseases studied.

Foundational Approach

- Process driven. Thriving for permanence
- Aligned with enterprise Health Equity goals
- Powered by Talent

Projected Outcomes

- Increased opportunity for ALL Patients
- Accelerated innovation and development
- Aligned with Health Authorities requests

BMS' Diversity in Clinical Trials Program progress

Objective:
Improve diverse patient recruitment, ensuring the participation in the Clinical Trial is more reflective of the real-world population and aligned with the epidemiology of the disease studied

Goal:

25% of US sites participating in new BMS clinical trials, need to be located in racially & ethnically diverse areas*

US Site and Investigator Selection

- Ensure our strategies and processes are aligned with the achievement of our external commitments.

Protocol Design Considerations

- Ensure clinical trial protocols minimize barriers to participation and follow FDA DiCT guidance.

Communications and Engagement

- Internal and external strategy framework by incorporating community groups, partnerships, and external thought partners.

Patient Support

- Reduce practical obstacles to clinical trial participation.

Training

- Internal and external Diversity, Equity and Inclusion training focusing on Clinical Trials

Metrics and Measures

- Track performance and ensure commitments are maintained

*Areas with more than 30% of nonwhite population

Case Study: Driving Increased Enrollment of Black Patients in Prostate Cancer Trials

The incidence of prostate cancer is about 60% higher in Blacks than Whites for reasons that remain unclear[1]

Tactics to Drive Diverse Patient Recruitment:

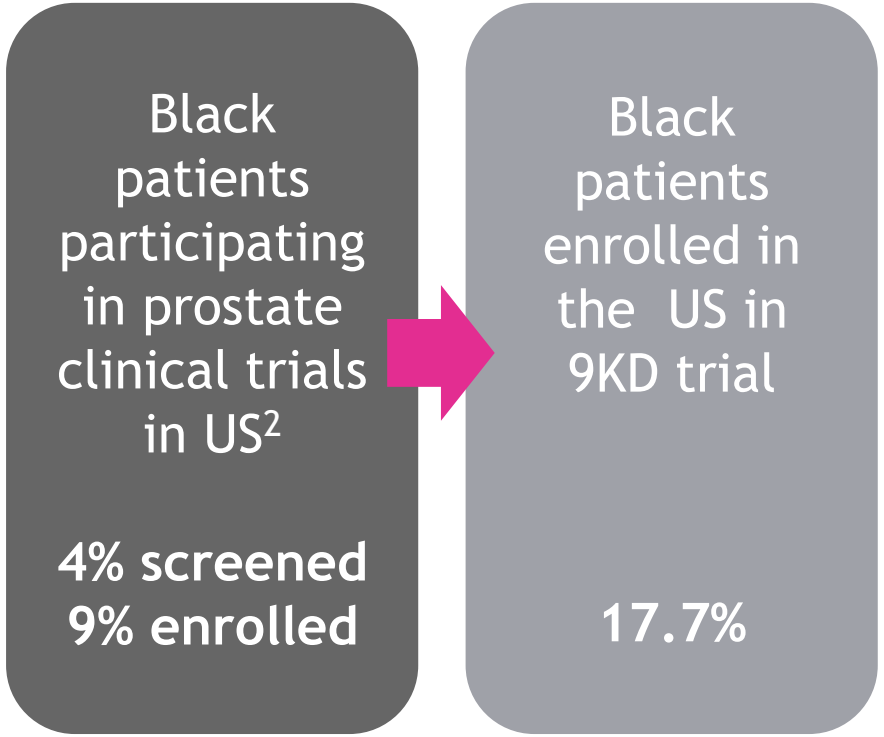
- Collaboration with advocacy and community based organizations to generate awareness about prostate cancer and clinical trials
- Targeted site selection in areas with increased black population

Other benefits:

- Increased interest in trials among black men
- Enhanced study design based on advice from Advocacy Organizations

Building on this model for the future:

- Consistent application in future prostate studies
- Communicate diversity strategy at Investigator Meetings
- Develop culturally appropriate materials



(1) Cancer Facts & Figures 2020
(2) Annals of Oncology, Volume 27, Issue 12, December 2016

Thank you