

# Clinical Trial Diversity February 24, 2021

## Moderator:

- **Kristin West**, Director, Research Ethics & Compliance, COGR

## Panelists:

- **Milena Lolic, MD, MS**  
Office of Chief Scientist  
Office of the Commissioner, FDA
- **Robert Fullilove, EdD**  
Associate Dean for Community & Minority Affairs  
Professor of Clinical Sociomedical Sciences  
Co-Director, Cities Research Group  
Columbia University
- **Efren Flores, MD**  
Assistant Professor of Radiology, Harvard Medical School  
Officer, Radiology Community Health & Equity  
Radiologist, Thoracic & Emergency Divisions  
Faculty, The Mongan Institute  
Massachusetts General Hospital
- **Martha Jones, MA, CIP**  
Vice President, Human Research Affairs  
Mass General Brigham
- **Megan Kasimatis Singleton, JD, MBE, CIP**  
Associate Dean, Human Research Protections and  
Director of the Human Research Protections Program  
Johns Hopkins University School of Medicine

# Advancing Trials Diversity Through Data Transparency

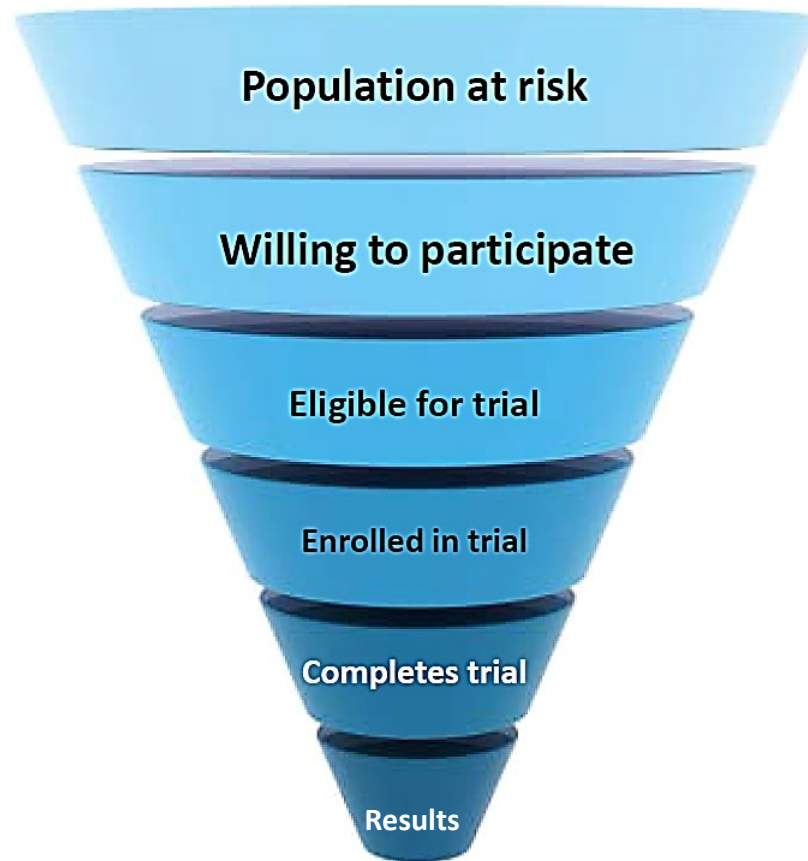
Milena Lolic, M.D., M.S.  
OCS-FDA

Council on Governmental Relations Virtual Meeting  
February 24, 2021

# Disclaimer

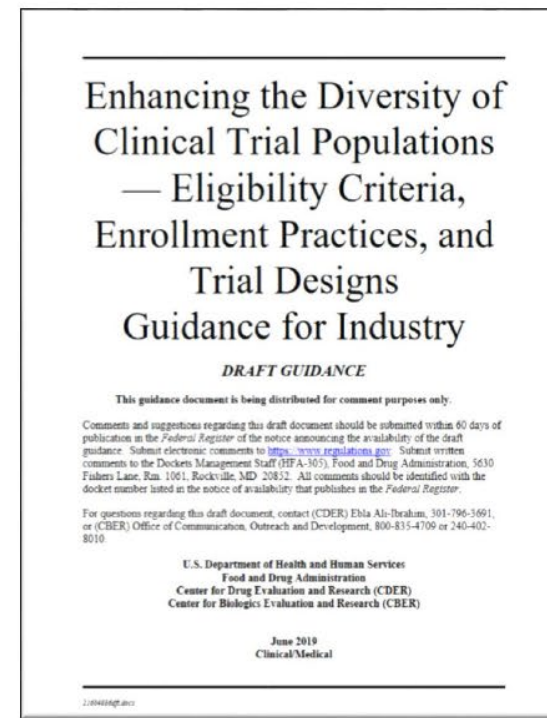
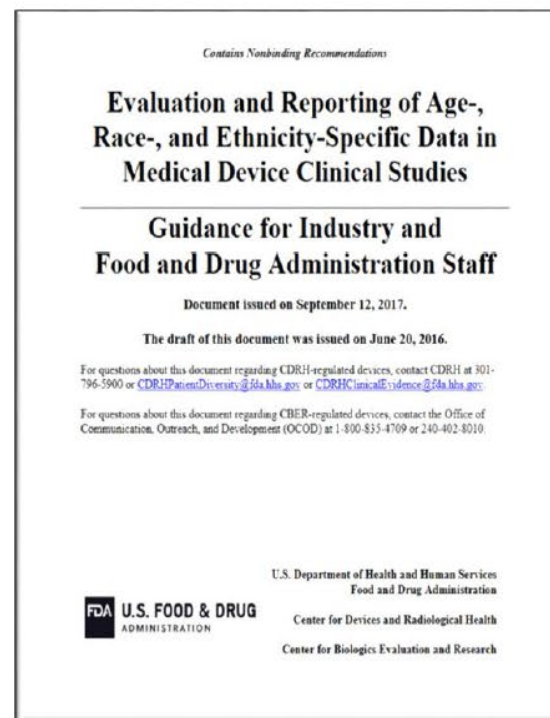
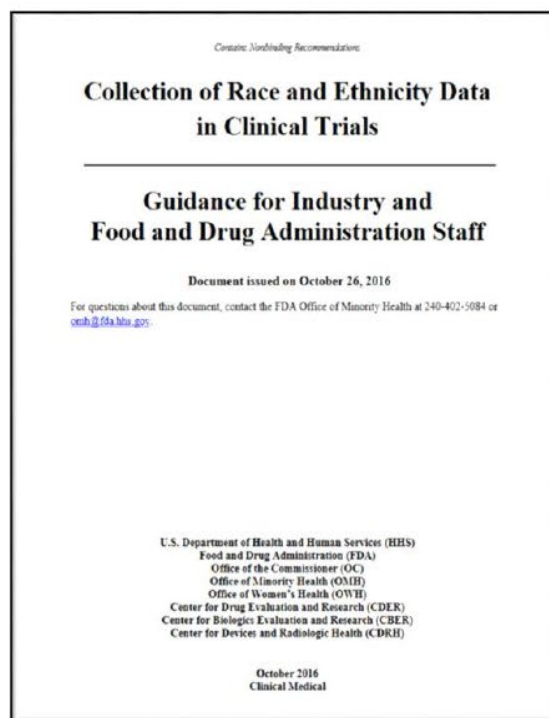
- This presentation represents the personal opinions of the speaker and does not necessarily represent the views or policies of FDA
- No conflicts of interest to declare

# Judging the Trial Data



- Rare disease
- ?
- Screen failure rates
- Barriers
- Drop-out rates
- Limited subpopulation conclusions

# Guidance Documents for Industry



# Drug Trials Snapshots

## Transparency effort since 2015

- Web-based information about participation in clinical trials that supported the FDA approval of new drugs\*
- Includes trial design, overall and subgroup assessments of safety and efficacy
- Dual format (for consumers and professionals)

\*New Molecular Entities and original Biologic Licensing Applications

# DRUG TRIALS SNAPSHOTS



Search:

Export Excel

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10



entries

Drug Trials Snapshot	Active Ingredient	Date of FDA Approval	What is it Approved For	Prescribing Information
<a href="#">ACCRUFER</a>	ferric maltol	July 25, 2019	Treatment of low iron stores	<a href="#">Accrufer</a>
<a href="#">ADAKVEO</a>	crizanlizumab-tmca	November 15, 2019	Treatment of vasoocclusive crises in patients with sickle cell disease.	<a href="#">Adakveo</a>
<a href="#">ADDYI</a>	flibanserin	August 18, 2015	Treatment of acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women	<a href="#">Addyi</a>
<a href="#">ADLYXIN</a>	lixisenatide	July 27, 2016	Improvement of blood sugar control in adults with diabetes mellitus (DM) type 2 when used in addition to diet and exercise	<a href="#">Adlyxin</a>
<a href="#">AEMCOLO</a>	rifamycin	November 16, 2018	Treatment of traveler's diarrhea in adults	<a href="#">Aemcolo</a>
<a href="#">AIMOVIG</a>	erenumab-aooe	May 17, 2018	Preventive treatment of migraine in adults	<a href="#">Aimovig</a>
<a href="#">AJOVY</a>	fremanezumab-vfrm	September 14, 2018	Preventive treatment of migraine in adults	<a href="#">Ajovy</a>
<a href="#">AKLIEF</a>	trifarotene	October 4, 2019	For the topical treatment of acne vulgaris in patients 9 years of age and older	<a href="#">Aklief</a>
<a href="#">AKYNZEO</a>	fosnetupitant and palonosetron	April 19, 2018	Prevention of the nausea and vomiting that happens right away or later in adults receiving certain anticancer medicines (chemotherapy)	<a href="#">Akynzeo</a>
<a href="#">ALECENSA</a>	alectinib	December 11, 2015	Treatment of metastatic non-small cell lung cancer	<a href="#">Alecensa</a>

Showing 1 to 10 of 275 entries

Previous

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4

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...

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Next

# DTS Summary 2015-2020

	WOMEN	WHITE	ASIAN	BLACK or AA	HISPANIC	AGE 65 and OLDER	USA
2015	40%	79%	12%	5%	-	37%	28%
2016	48%	76%	11%	7%	-	21%	43%
2017	55%	77%	11%	7%	14%	32%	34%
2018	56%	69%	10%	11%	14%	15%	47%
2019	72%	72%	9%	9%	18%	36%	40%
2020	56%	75%	6%	8%	11%	30%	54%

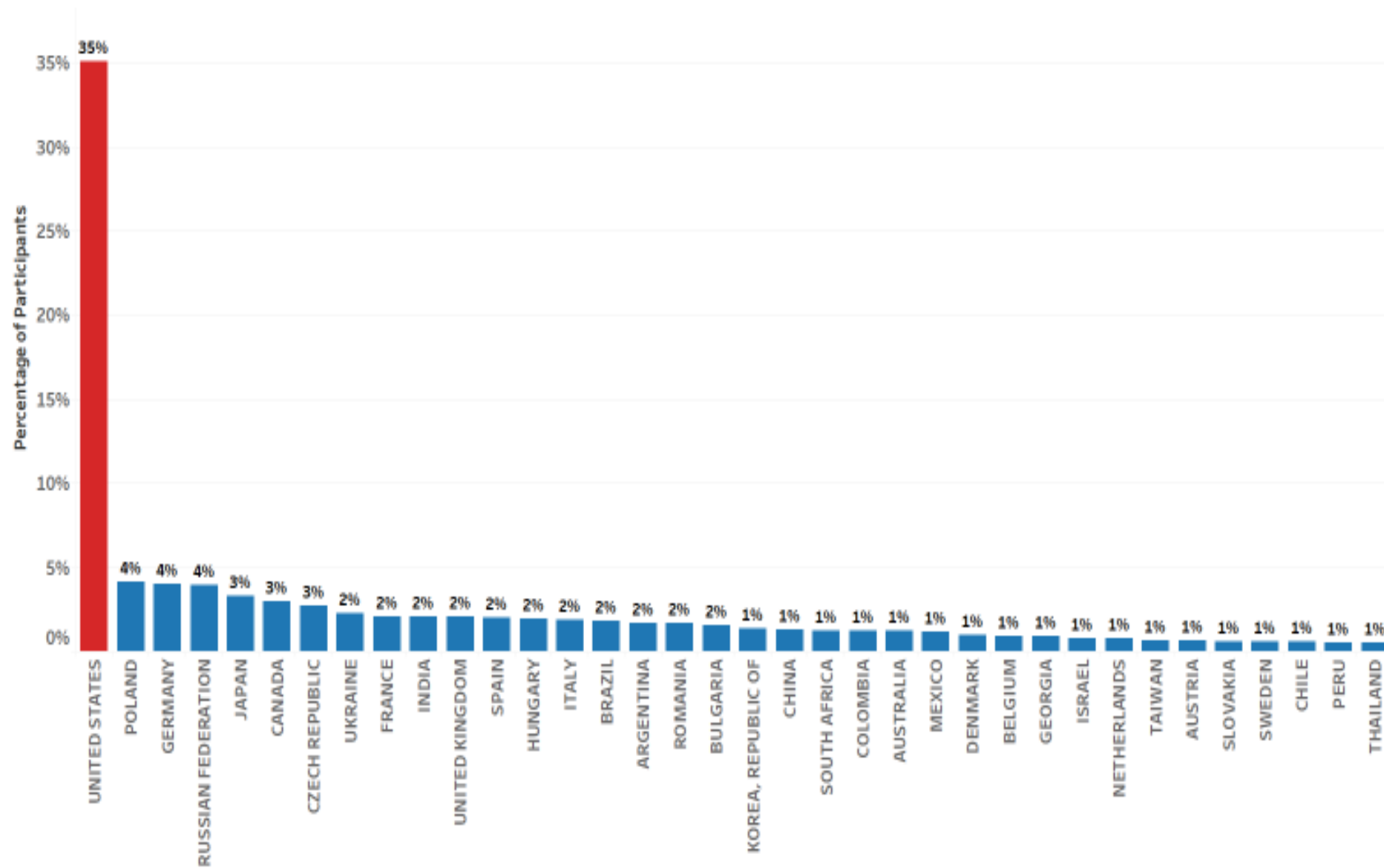


2015-2019  
**DRUG TRIALS SNAPSHOTS**  
**SUMMARY REPORT**

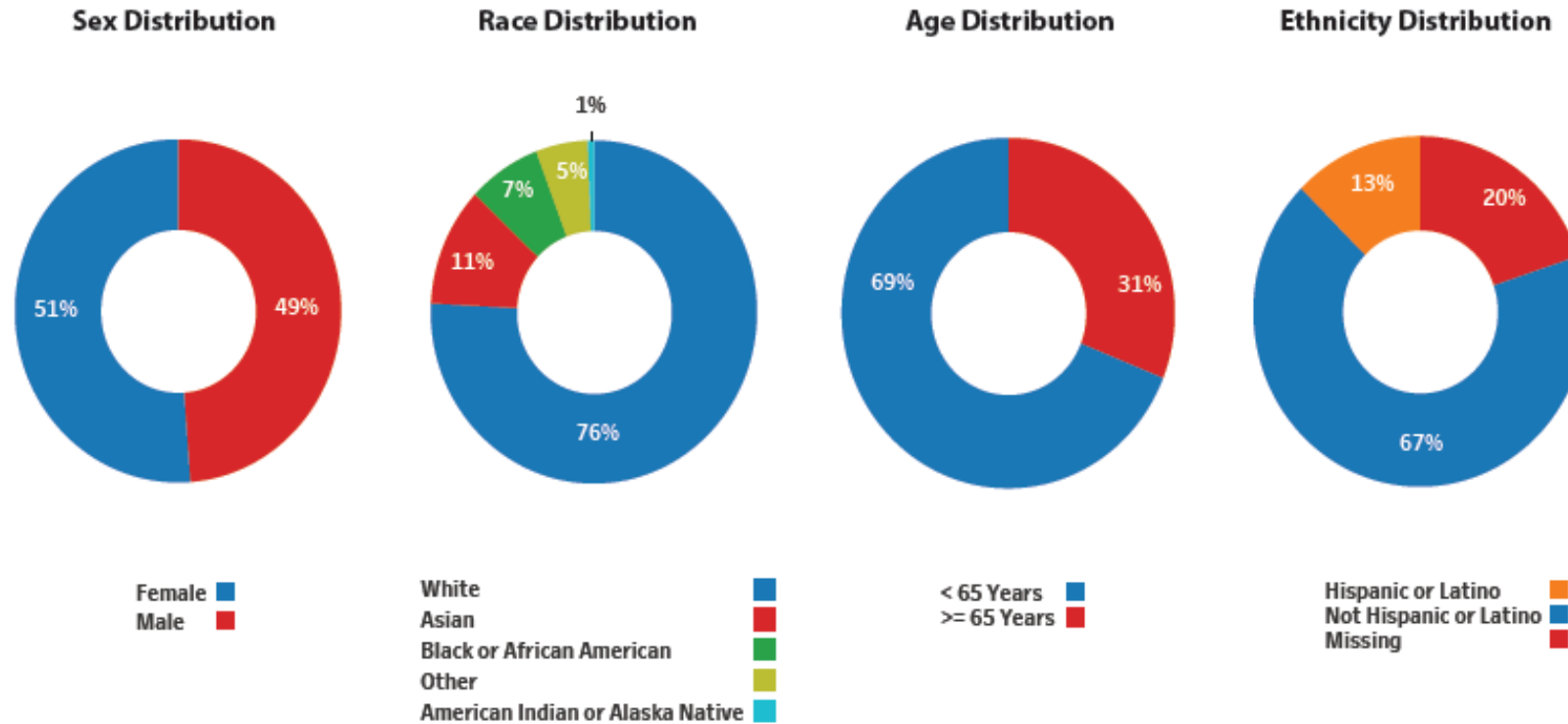
Five-Year Summary and Analysis of Clinical Trial Participation and Demographics

# Trial Participants by Country

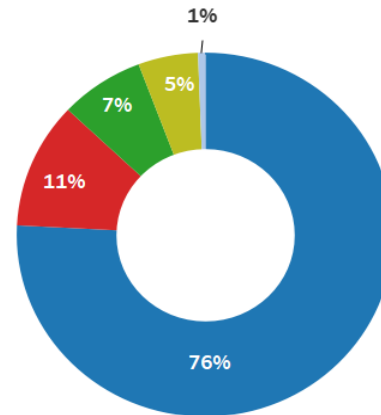
United States ■  
Rest of the World ■



# Global Demographics

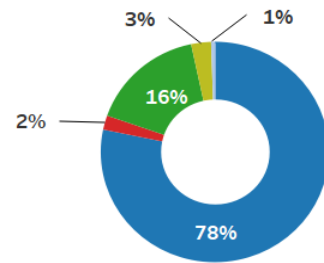


### Race Distribution

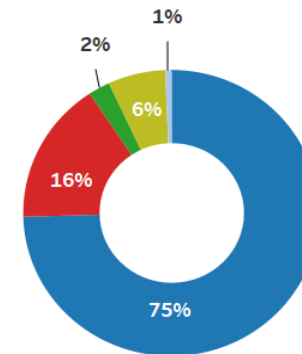


**Global**  
Total Participants = 292,537  
(Country data missing for 229 participants)

White  
Asian  
Black or African American  
Other  
American Indian or Alaska Native

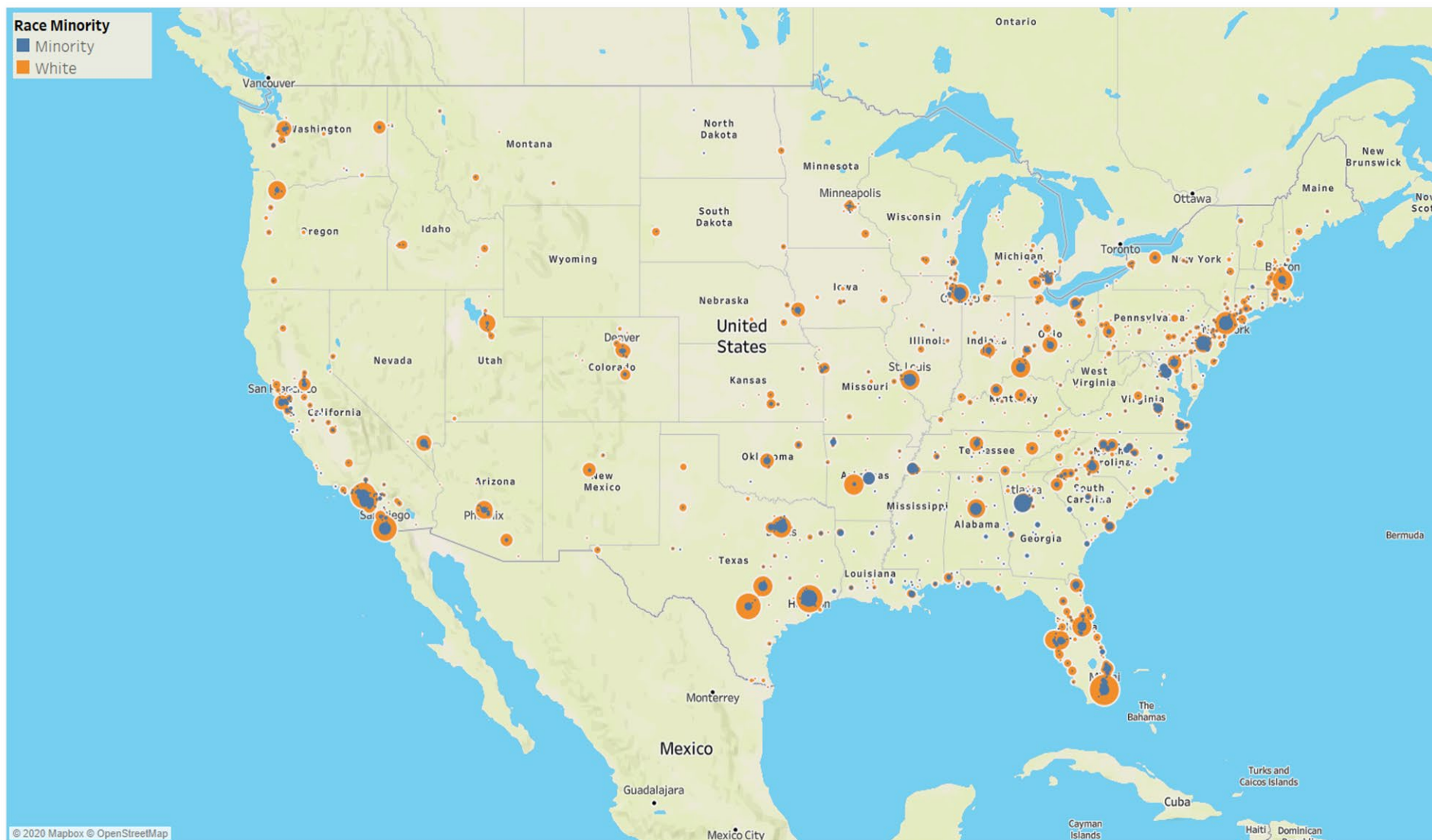


**United States**  
Total Participants = 102,595



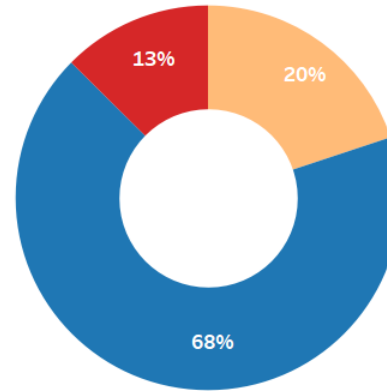
**Rest of the World**  
Total Participants = 189,942

# US Participation by Race



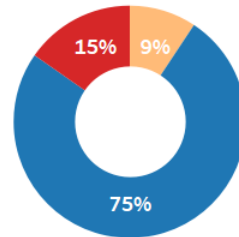
## Ethnicity Distribution

Not Hispanic or Latino  
Hispanic or Latino  
Missing



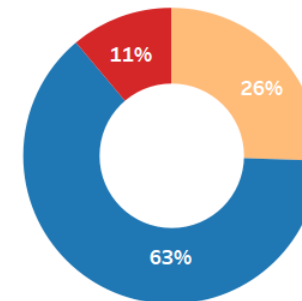
### Global

Total Participants = 292,537  
(Country data missing for 229 participants)



### United States

Total Participants = 102,595

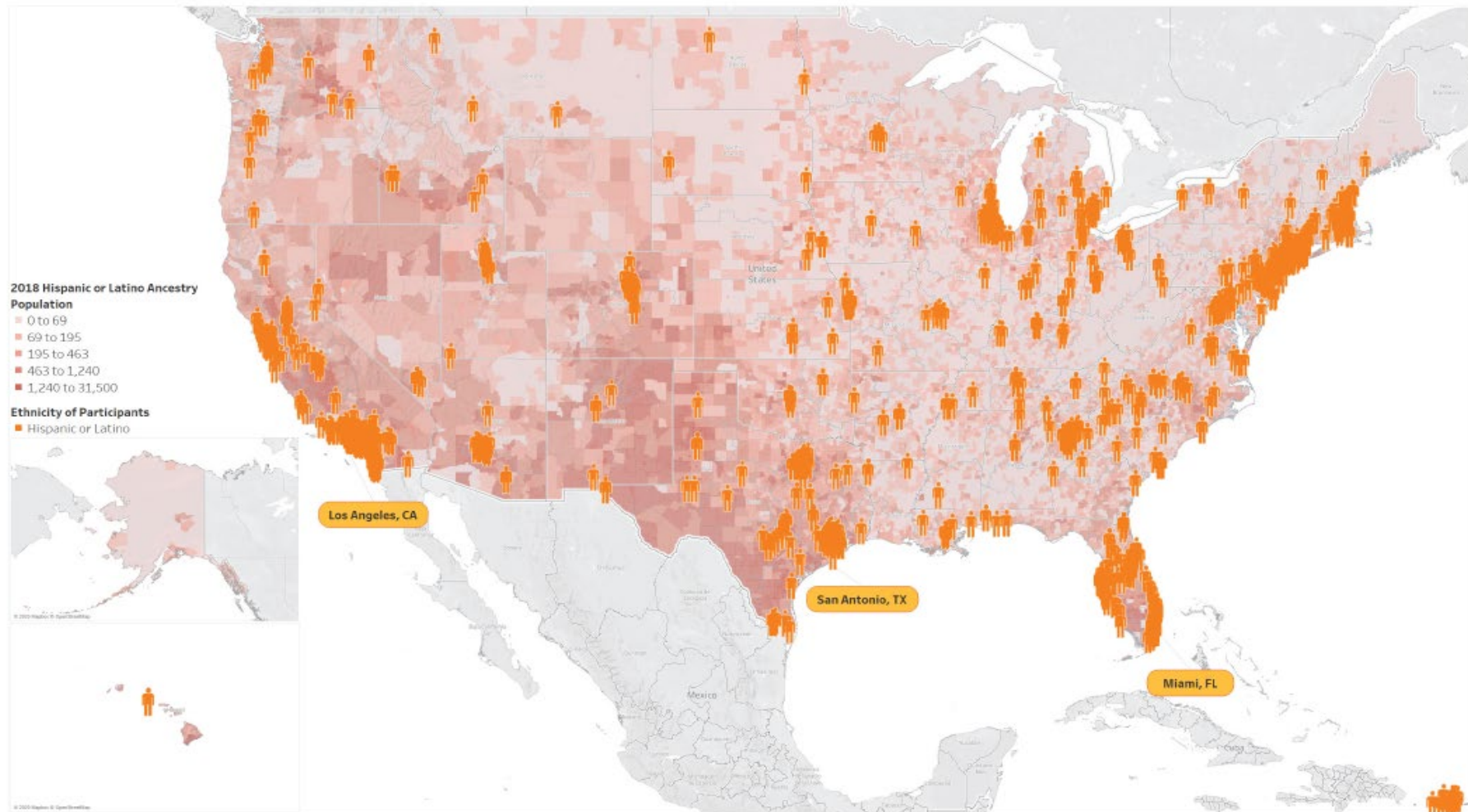


### Rest of the World

Total Participants = 189,942



# US Participation by Ethnicity



2015-2019 Drug Trials Snapshots Summary Report

# Oncology DTS Data-2020

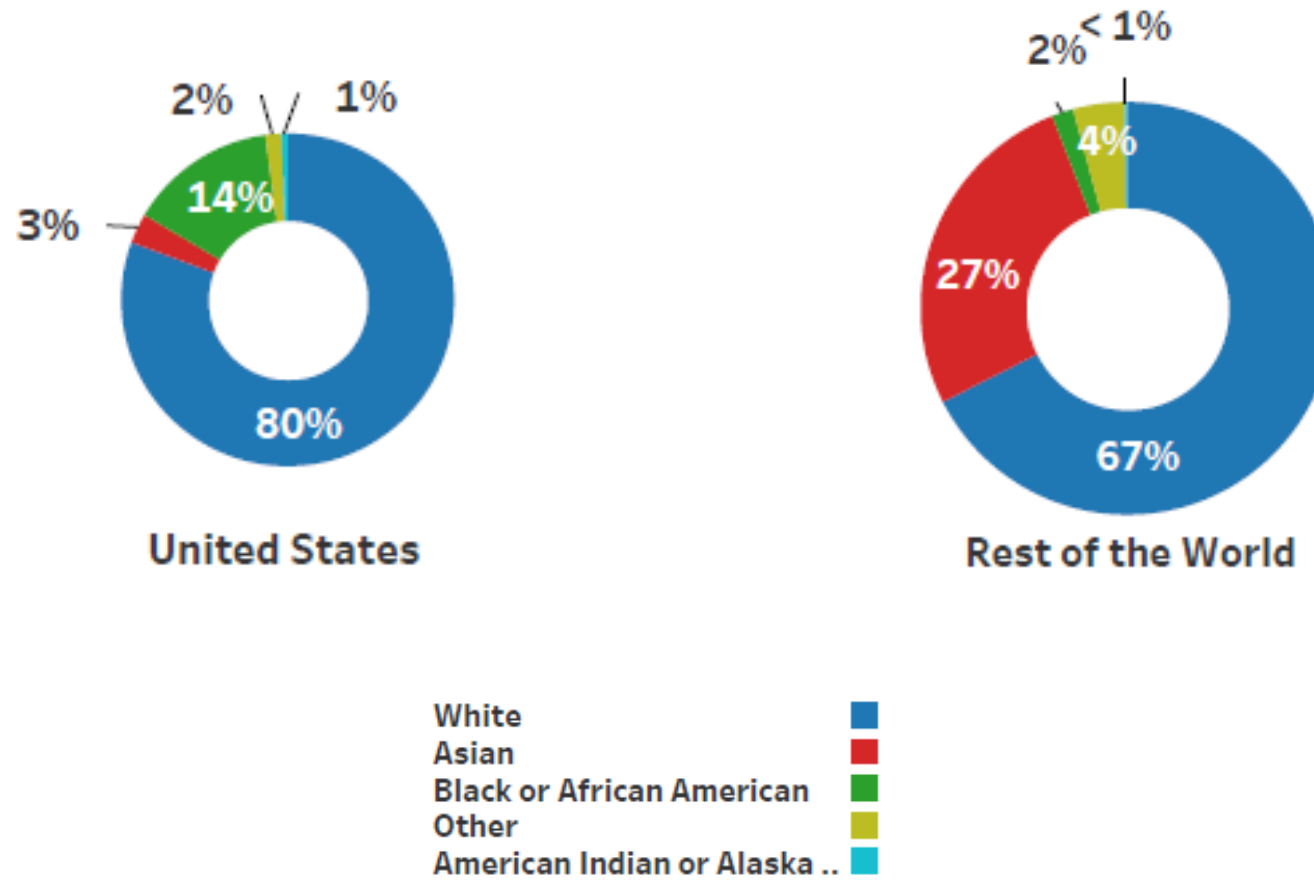


A total of 4,922 patients participated in the trials that led to the approvals of 18 new drugs. Overall,

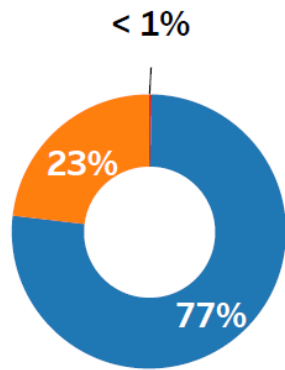
- 50% of all participants were women,
- 73% were White,
- 14% were Asian,
- 5% were Black or African American,
- 5% were Hispanic,
- 44% were 65 years and older, and
- 41% were from the sites in United States.



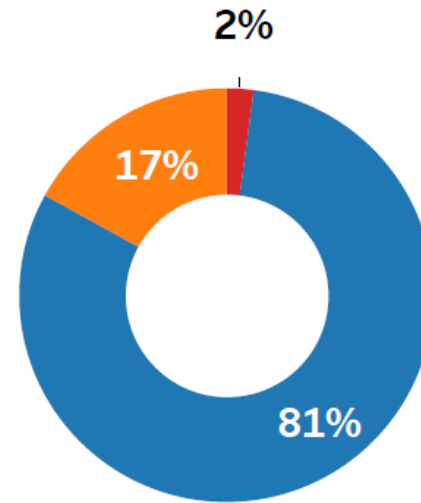
# Race Distribution in DM Trials



# Ethnicity Distribution in DM Trials



**United States**  
Total Participants = 7,350



**Rest of the World**  
Total Participants = 24,211

- Missing
- Not Hispanic or Latino
- Hispanic or Latino

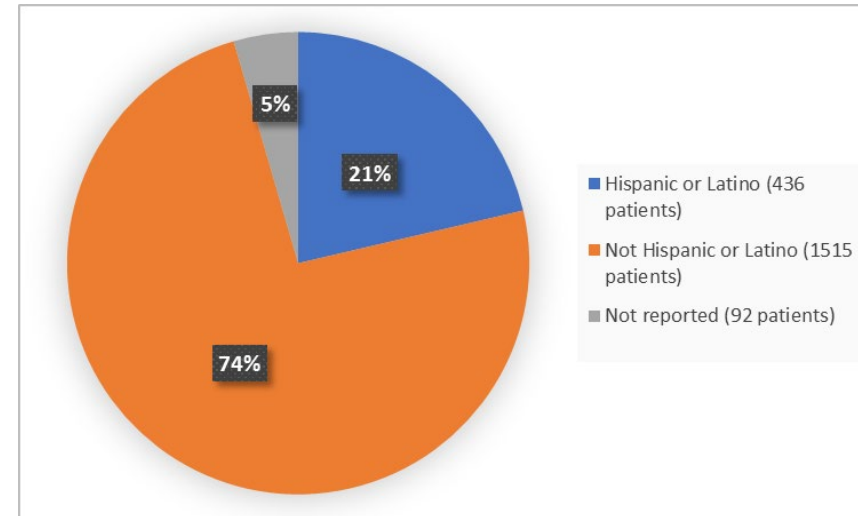
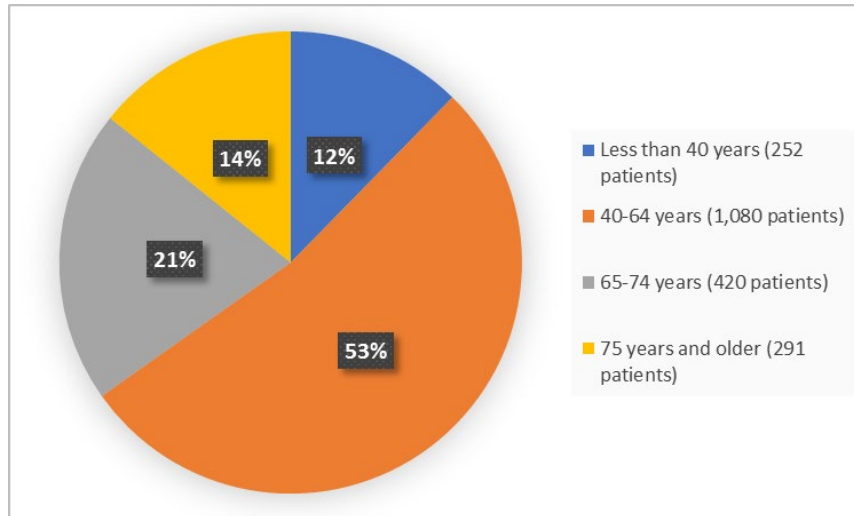
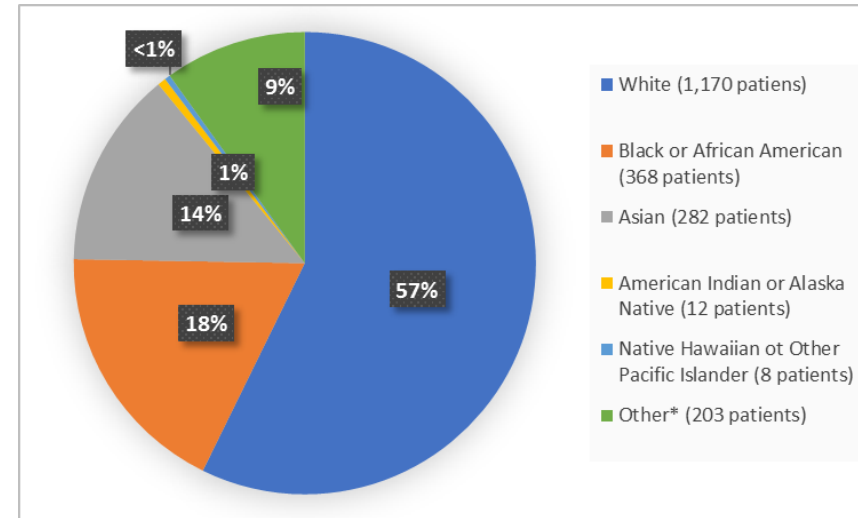
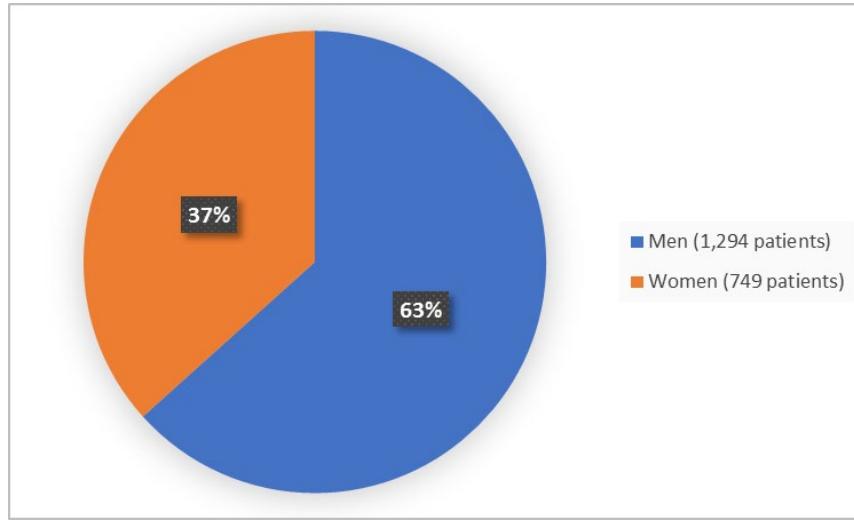
# Barriers to Participation

- Lack of awareness
- Mistrust of the medical system
- Inadequate recruitment effort
- Language barrier
- Barriers to the enrollment in clinical trials
  - enrollment criteria
  - sites selection
  - time and resource constrains

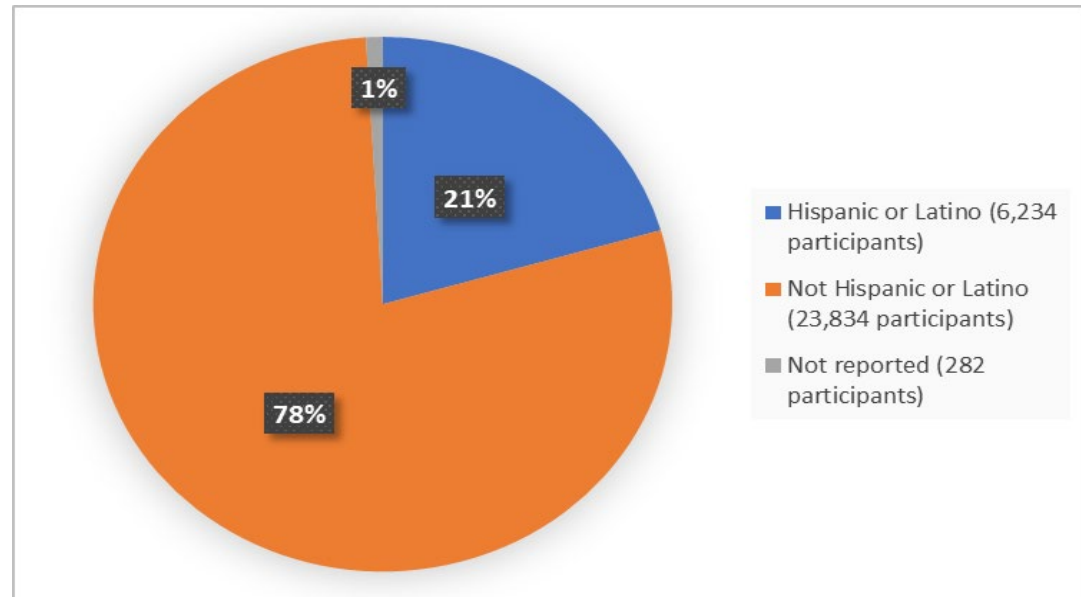
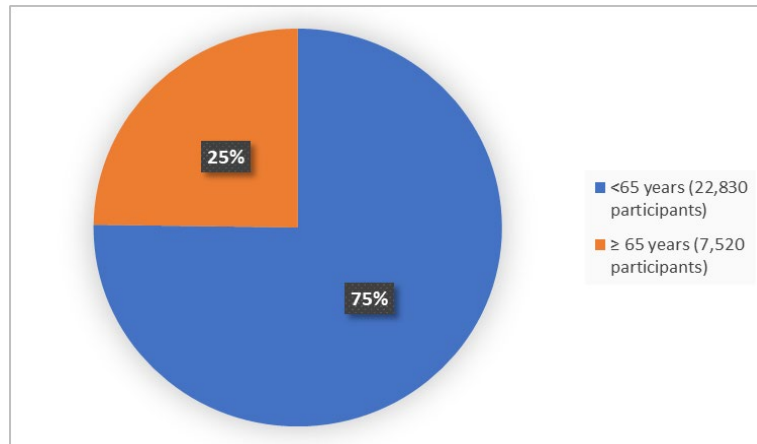
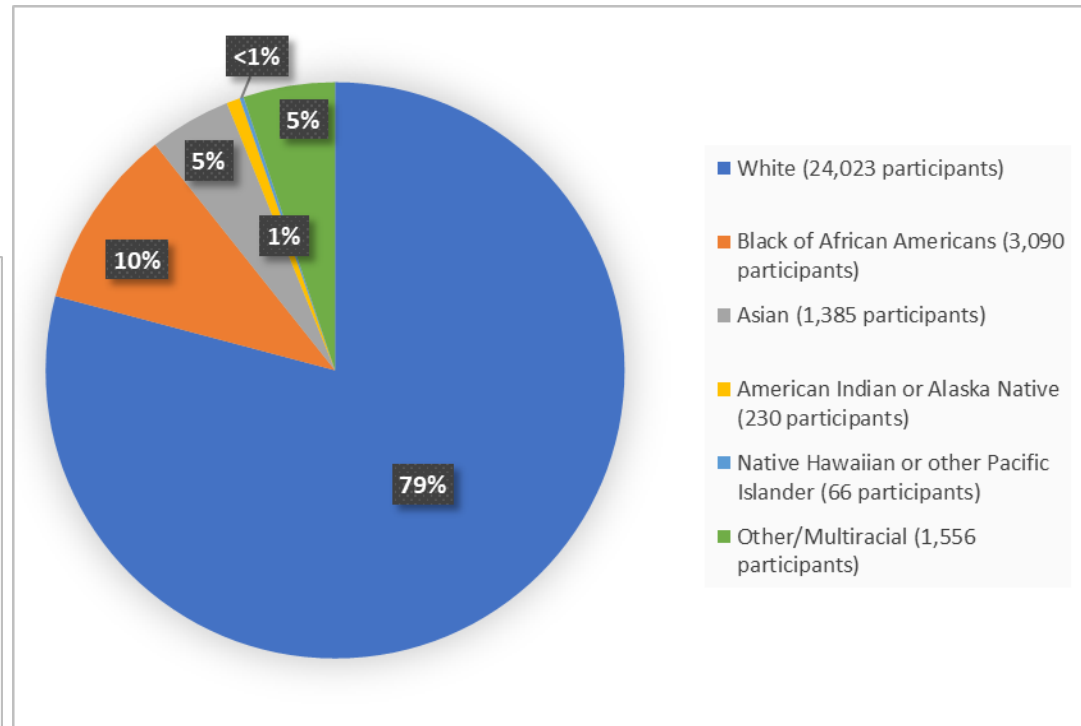
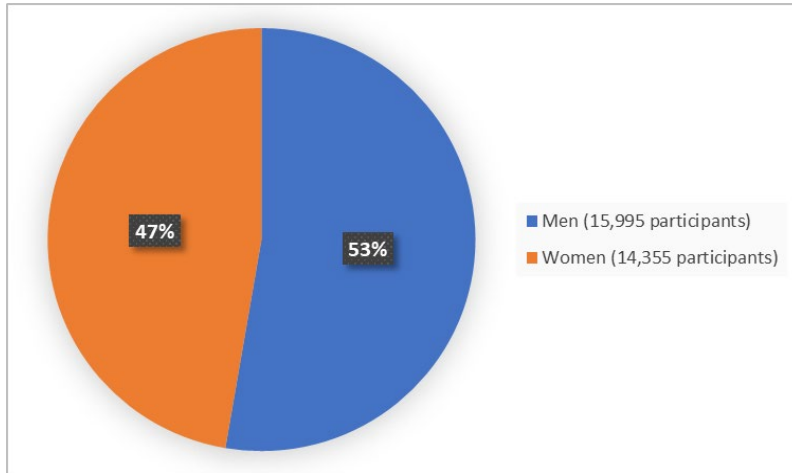
# COVID-19 and Diverse Population

- FDA Guidance for Industry on Development and Licensure of Vaccines to Prevent COVID-19; June 2020
  - “FDA strongly encourages the enrollment of populations most affected by COVID-19, specifically racial and ethnic minorities.”
- FDA Guidance for Industry on COVID-19: Developing Drugs and Biological Products for Treatment or Prevention; May 2020
  - “Racial and ethnic minority persons should be represented in clinical trials. Sponsors should ensure that clinical trial sites include geographic locations with a higher concentration of racial and ethnic minorities to recruit a diverse study population.”

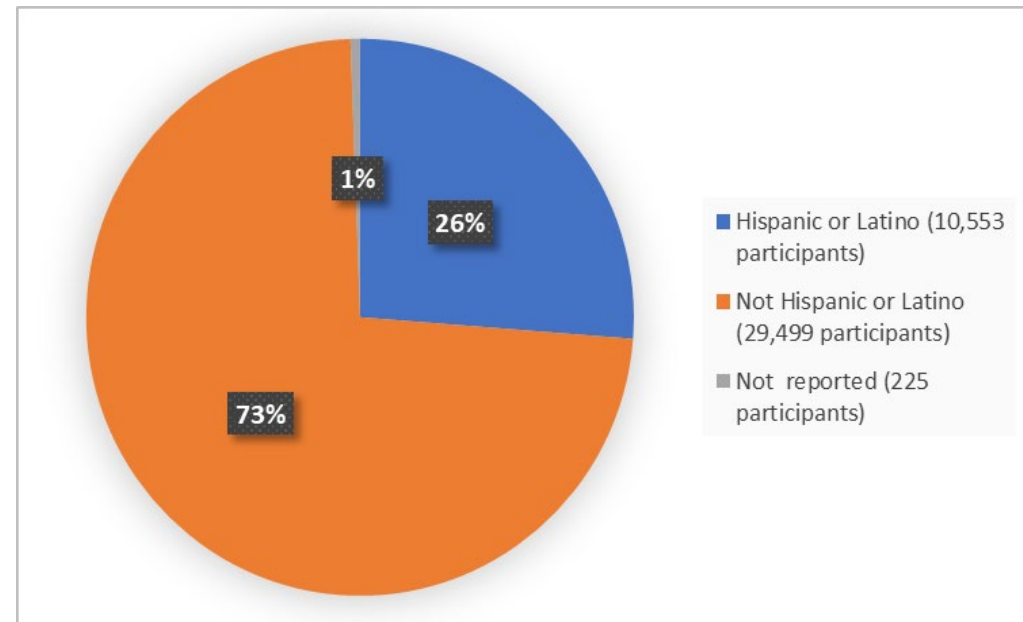
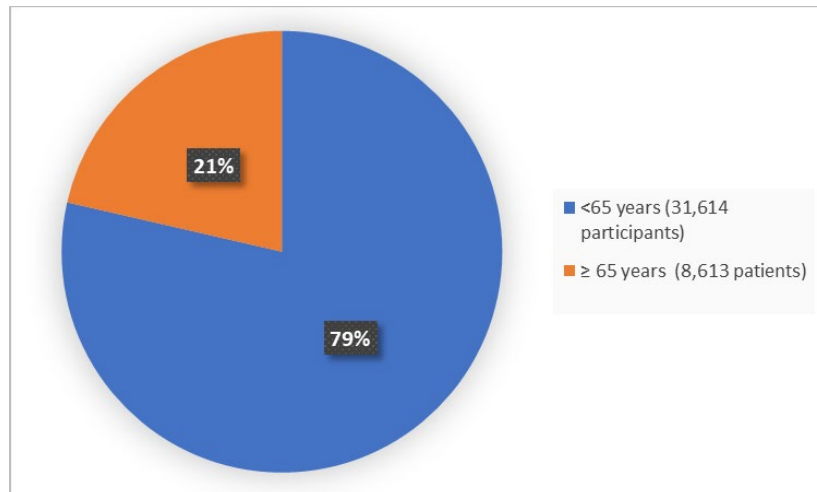
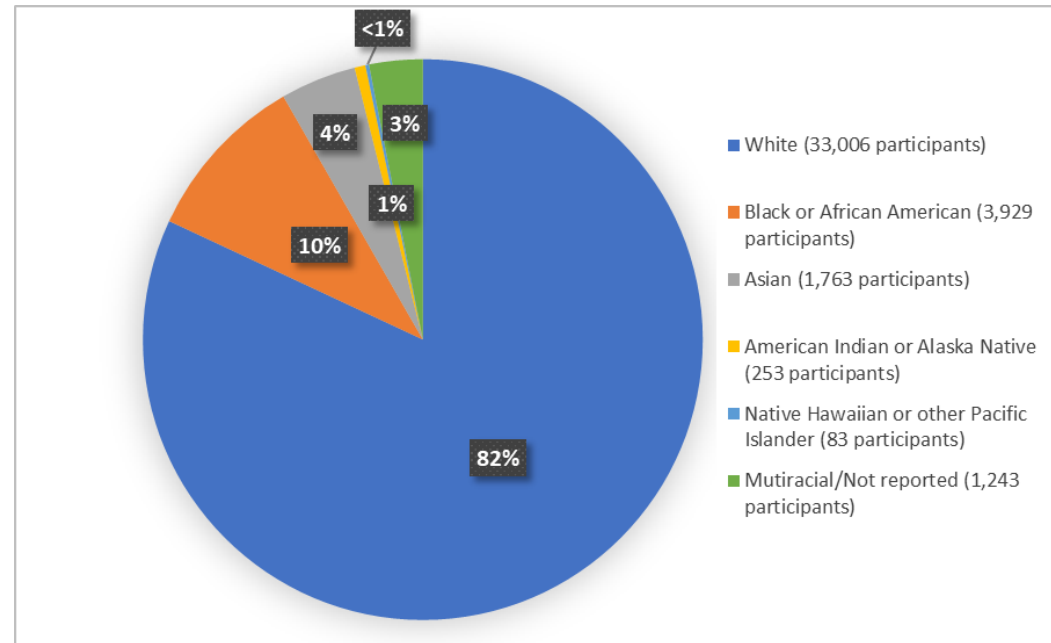
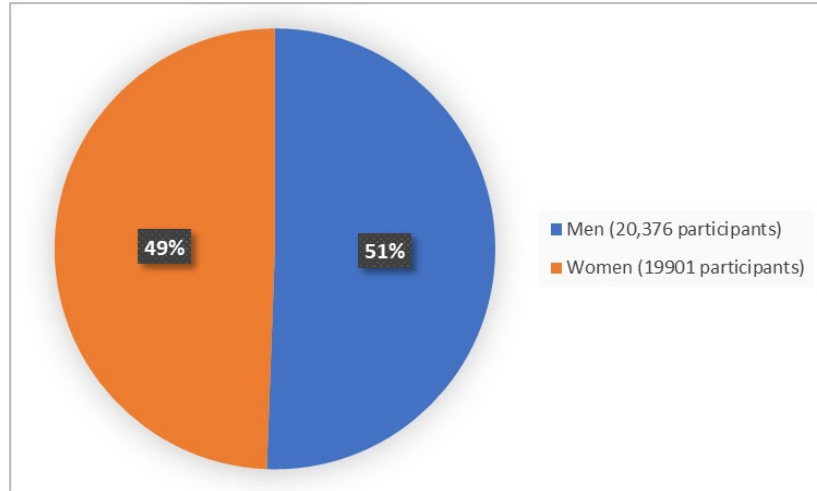
# Remdesivir Trials



# Moderna Trials



# Pfizer Trials



# Achieving Health Equity in Preventive Services

Screening rates are higher with

- patient navigator for colorectal, breast, and cervical cancer;
- telephone calls and prompts for colorectal cancer; and
- reminders with lay health workers for breast cancer.



# FDA OMHHE

## Research and Collaboration

- Intramural Research
- Extramural Research
- FDA Centers of Excellence in Regulatory Science and Innovation (CERSI) Projects
- Broad Agency Announcement (BAA)
- Summer Science Teacher Training Program
- Internships and Fellowships
- Academic Collaborations
- FDA & HHS Working Groups & Collaborations
- Stakeholder Input into Research Agenda

## Outreach and Communication

- Programs/Initiatives/Campaigns
  - Diversity in Clinical Trials Initiative
  - Language Access Program
- Health Education Materials
- Social Media
- Newsletter & E-alerts
- Website
- Health Equity Lecture Series & Webinars
- Stakeholder Meetings/Symposiums



Thank you

# Resources

- Drug Trials Snapshots

<https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots>

- NIH Clinical Trials

<https://www.ClinicalTrials.gov>

- FDA Guidances

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents>

- FDA Advisory Committee

<https://www.fda.gov/advisory-committees/advisory-committee-calendar>

- Office of Minority Health and Health Equity

[OMHHE@fda.hhs.gov](mailto:OMHHE@fda.hhs.gov)

# Q & A

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A close-up, shallow depth-of-field photograph of a white plastic test tube rack. The rack contains several test tubes with colorful caps (blue, purple, orange, yellow) and white labels with black barcode patterns. The tubes are arranged in rows, and the focus is sharp on the tubes in the foreground, with the background tubes blurred.

# IMPROVING DIVERSITY IN CLINICAL TRIALS: HOW DO WE DO THAT?

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ROBERT E FULLILOVE, EdD

Columbia University

# Positionality: what's my credibility?

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- I have had more than a little experience with our nation's struggles with diversity and with efforts to have anti-racist approaches to medicine and public health
- For this topic, it is important to understand that the resistance to participate in scientific research in the Black community involves more than an awareness of the Tuskegee Syphilis Study..



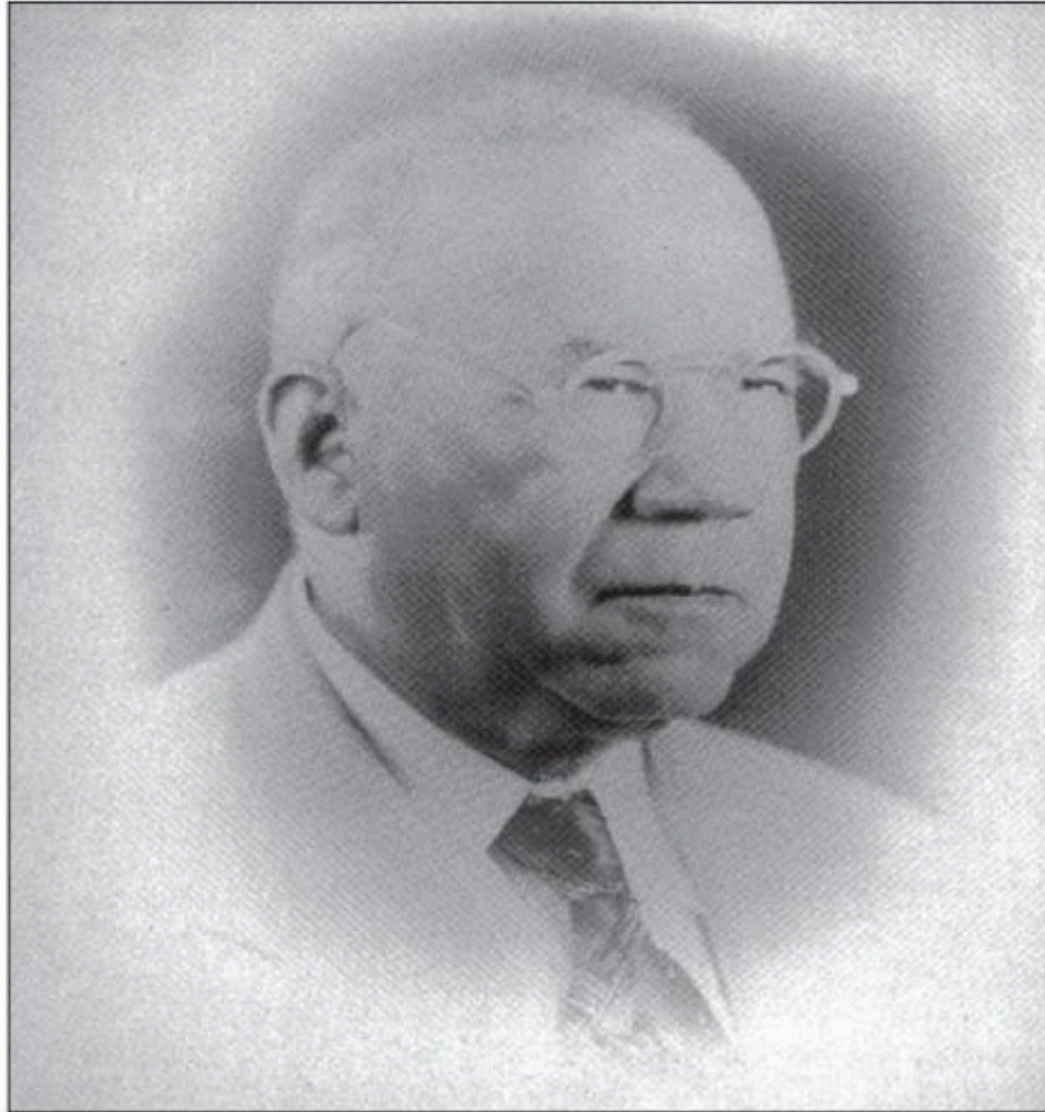


**Figure 5.** Afro-American Sons and Daughters Hospital circa 1950  
(Reproduced with permission; *Afro-American Sons & Daughters*; Joseph C. Thomas, author)





**Figure 3. Robert Elliott Fullilove, MD**  
(Reproduced with permission; *Afro-American Sons  
& Daughters*; Joseph C. Thomas, author)



# Treating Spanish Flu, Mississippi Delta 1918

During the very terrible epidemic of the flu that claimed my mother's life, my father spent three days and nights going from one plantation to another, without going home at all. He would finish at one house where all the members were down with the flu, and there would be somebody waiting there to take him to another house where all the members were sick. And, surprisingly enough, although we had it, she died of it, he never contracted at all.

# Julius Rosenwald Fellows

MGH Dates of Note: 1938-1940

## *Harold E. Farmer, MD*

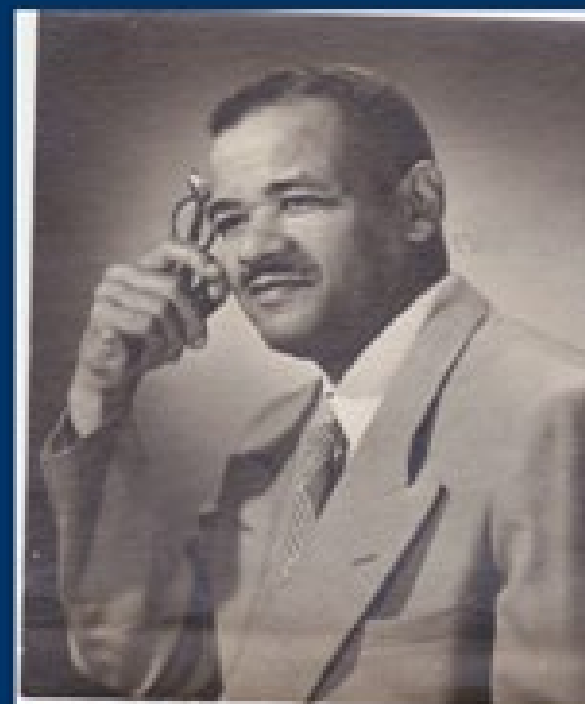
Internal Medicine, 1938

1932 – Graduated from University of Pennsylvania School of Medicine

## *Robert E. Fullilove, Jr., MD*

Urology, 1940

- 1934 – Graduated from Howard Medical School
- First African American elected president of the Essex County Medical Hospital



Robert Fullilove, MD (above),  
courtesy of his son, Robert  
Fullilove, PhD

# My Dad's first publication: JAMA, 1943

## Article

July 10, 1943

## "SYPHILIS AND THE NEGRO"

Robert E. Fullilove Jr., M.D.

### » Author Affiliations

*JAMA*. 1943;122(11):764. doi:10.1001/jama.1943.02840280048022

### "SYPHILIS AND THE NEGRO"

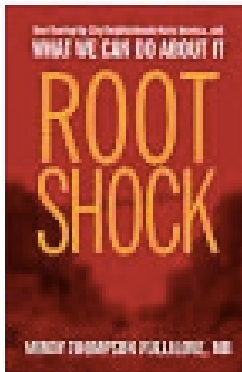
*To the Editor:*—The article by Dr. Smillie in the June 5 issue of THE JOURNAL concerning syphilis and the Negro, and the editorial comment, serve to give needed emphasis to an important problem. But in characterizing the problem as a purely Negro one there is grave danger of overlooking some important facts concerning the treatment and prevention. Why is the syphilis rate so much higher in the Negro than in the white? To quote Dr. Smillie, "Among the whites syphilis has become, in the great majority of cases, a disease of the ignorant, the careless, the criminal and the social outcast." Do not the same conditions apply to syphilis in any group? The Negro is discriminated against economically and educationally; it would be difficult to find conditions more favorable to the development of crime, carelessness and social ostracism than the poverty and ignorance engendered by the wage and educational differentials that are too often the lot of the Negro. In this connection the chart published with your editorial comment (p. 378) is quite significant. It shows educational deficiencies as a cause, second only to syphilis, of rejection of Negro males by Selective Service local boards, whereas this factor did not appear in the first ten causes of rejection in the white group. This is more than a mere coincidence. It would be a serious mistake to attempt to treat this problem by merely dispensing large quantities of antisyphilitic drugs without at the same time attempting to cure some of the serious socioeconomic conditions underlying it.

ROBERT E. FULLILOVE JR., M.D., New Orleans.

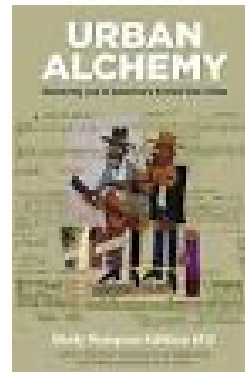


**Mindy  
Thompson  
Fullilove, MD**

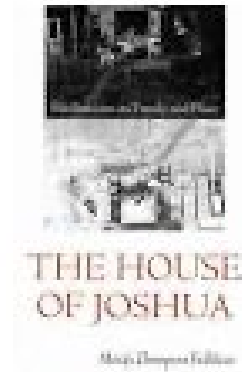
# Books by Mindy Thompson Fullilove, MD



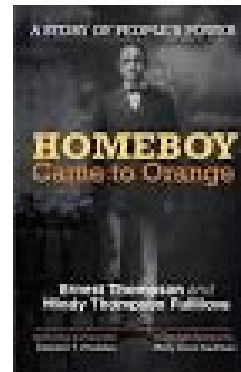
Root shock  
2004



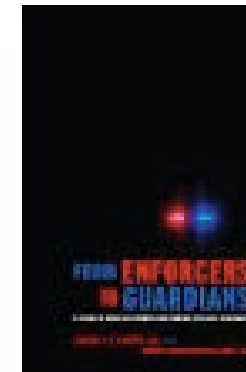
Urban  
Alchemy:  
Restorin...  
2013



The house  
of Joshua  
1999



Homeboy  
Came to  
Orange...  
2008



From  
Enforcers  
to Guard...  
2020



"Taut and involving ... *Freedom Summer* bristles with fine details."

— THE NEW YORK TIMES

The Savage Season of 1964 That Made Mississippi Burn  
and Made America a Democracy



Bruce Watson

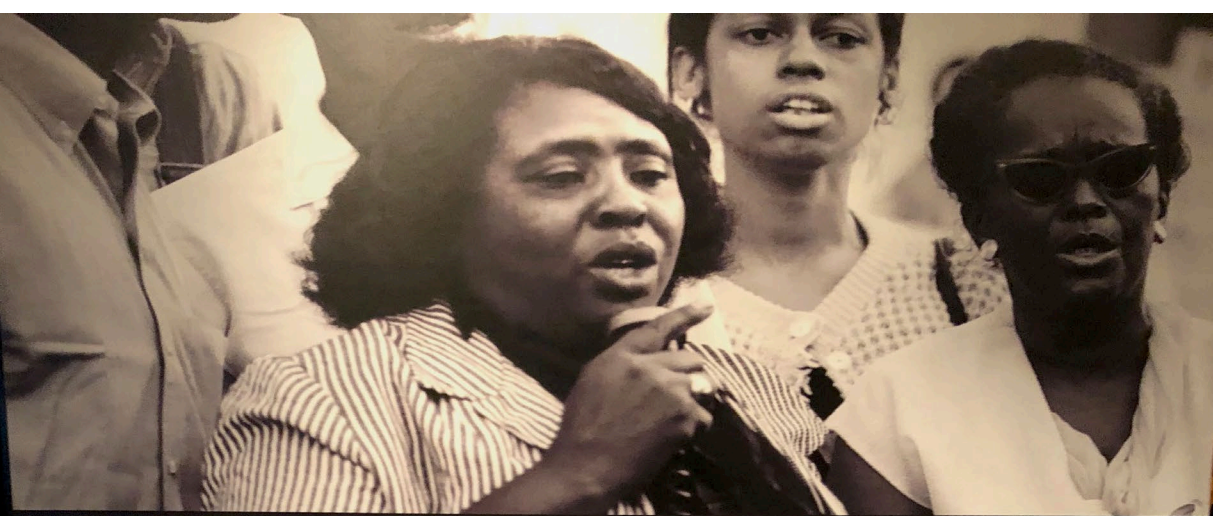
Author of *SACCO AND VANZETTI*

# FREEDOM SUMMER









Mississippi Freedom Democratic Party delegates at the Democratic National Convention in Atlantic City, New Jersey. © 1964 George J. Johnson

## 1964

The summer of 1964 saw steady strides forward in the struggle for justice and equality. Civil rights organizations established a summer program to help African Americans register to vote in Mississippi. The Mississippi Freedom Democratic Party was born to challenge the traditional Democratic Party in the state, which was dominated by segregationists. And in July the Civil Rights Act proposed by President John F. Kennedy before his assassination was signed into law by President Lyndon Johnson.

Johnson, after signing the 1964, continues progress for civil rights and equality.

Johnson, after signing the 1964, continues progress for civil rights and equality.

## Freedom Summer

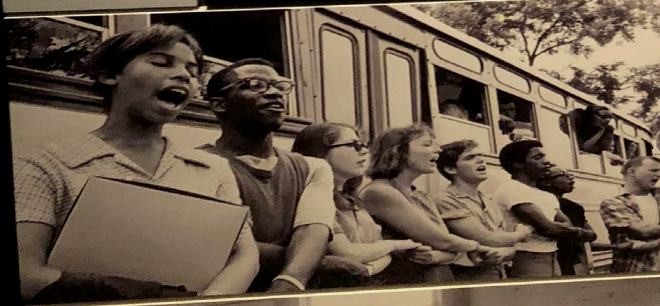
Bob Moses of the Student Nonviolent Coordinating Committee began working on voter registration in rural Mississippi in 1961, with limited success. To help register black voters and attract more national attention, Moses and his colleague Al Lowenstein, a white lawyer educated at Yale University, recruited mostly white northern college students to join them in the Mississippi Summer Project, also known as Freedom Summer. The project founded dozens of Freedom Schools for rural students, and helped several thousand African Americans as they tried to register to vote.

Robert Roper from a Liberty House catalog



Distributor of hand-crafted products by Poor People from: Mississippi, Louisiana, Florida, Georgia, Alabama as well as Africa, Mexico, Guatemala, Canada and other parts of the world.

**LIBERTY HOUSE**



# Perceptions of scientific research

- Science has become “just another voice in the room”
- It is no longer perceived as a source of undeniable truth
- In communities of color, residents question: “what has scientific research done concretely for me or mine?”

# Medicine, public health, and clinical research in the age of COVID-19

- The pandemic has demonstrated how poorly medicine and science have served communities of color
- Residents of such communities are overrepresented among cases, hospitalizations, and mortality rates
- Vaccine distribution has not fared any better: poor access, limited availability, well-documented abuses, and a history of vaccine hesitancy are just some of our current challenges

# Relevant comments from community members

- “I only see you when you want something. You want me in an experiment that you say will help me and my community.”
- “But if you want to help my community, do something first about unemployment, housing, educational opportunities, and these racist cops....”

# What is the most important first step?

- Creating a sense of trust that we are in communities of color to do more than conduct research
- Without a coordinated effort to be in such communities to be visible allies working on ALL of the community's problems, our silos will keep us from creating effective collaborations

# What's needed?

- A Marshall Plan for community public health interventions
- COVID-19 provides the perfect opportunity to collaborate
- A concerted plan to eliminate the health disparities and the social determinants of health that COVID-19 has exploited is urgently needed

# What is needed?

- Concerted efforts to deal with all of the health needs of the community are a fundamental component of creating trust.
- Impossible? Too difficult to organize? Our silos prevent collaboration? Ok, but...
- Necessity is the Mother of Invention...and so is our need to get on top of this pandemic....





# Promoting diversity and equity in clinical trials

**Efrén J. Flores, MD**

Assistant Professor of Radiology, HMS  
Officer, Radiology Community Health & Equity  
Faculty, The Mongan Institute  
Radiologist, Massachusetts General Hospital



**@EJFLORESMD**



# BARRIERS TO RESEARCH

Quote from individual interview with  
Hispanic/Latina “passive refuser” for a clinical trial:  
“Before talking to you, no one has asked me to  
participate in research”

## Barriers to research

"They don't want to be anyone's guinea pig." - *Patient Navigator*

**MISTRUST**

"No, I've never been offered a research study" - *Patient*

**~~OPPORTUNITIES~~**

"Many of them don't have Patient Gateway. Some of them don't even have smart phones" - *Provider*

**TECHQUITY**

## Barriers to care

"Medicaid does not want to give you MRIs and CT scans. You have to be on your deathbed." - *Patient*

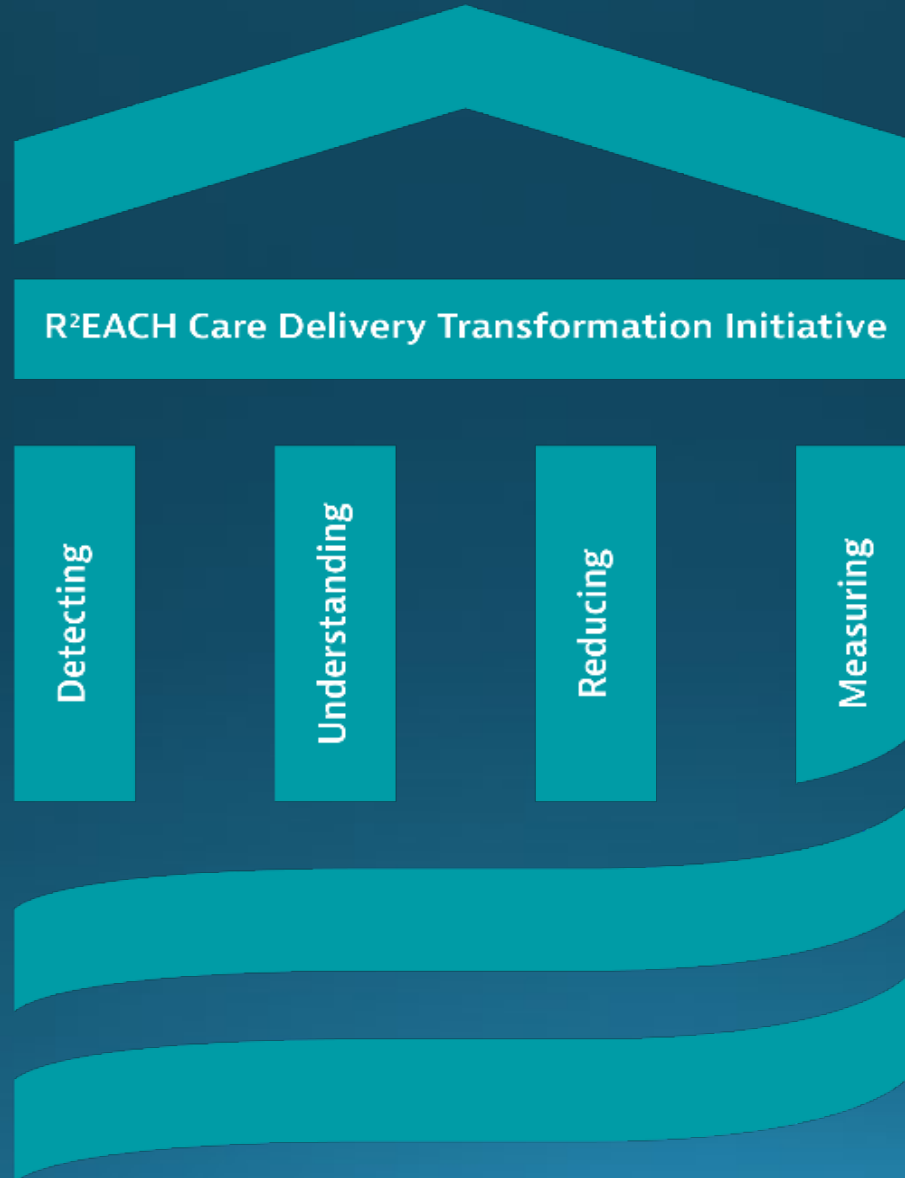
"I mean, how do you just go about asking a doctor to get a lung screen?" - *Patient*

"I don't have a computer. I don't have internet access or anything like it." - *Patient*



MEETING PATIENTS  
WHERE THEY ARE

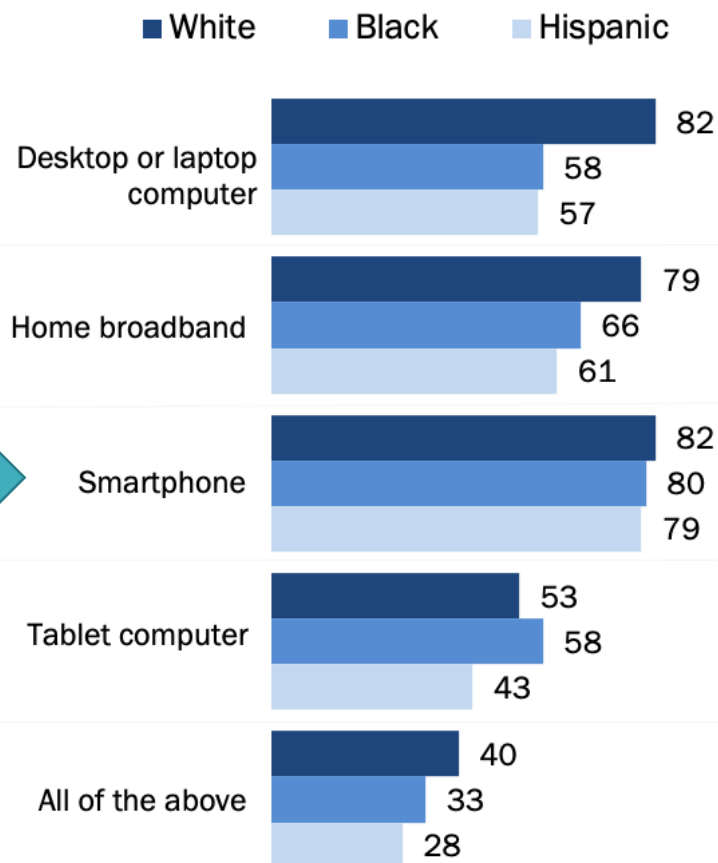
# Radiology Race, Equity, Access & Community Health (R<sup>2</sup>EACH) Care Delivery Transformation Initiative





## Despite some lower adoption, blacks and Hispanics own smartphones at similar shares to whites

*% of U.S. adults in each group who say they have the following*



Note: Those who did not answer are not shown. Whites and black include only non-Hispanics. Hispanics are of any race.

Source: Survey conducted Jan. 8-Feb. 7, 2019.

PEW RESEARCH CENTER

- Digital outreach and telemedicine can be a vehicle to promote equity and diversity
- Transforming recruitment and engagement in research requires a new approach



# Promoting diversity and equity in research and clinical care

## LUNG CANCER SCREENING ARE YOU ELIGIBLE?



Latino Provider



Latina Patient

## EXÁMENES DE DETECCIÓN DE CÁNCER DE PULMÓN ¿ES USTED CANDIDATO?

¿SU EDAD?

Simpler  
language  
with  
more  
visuals

¿FUMA?



Tobacco Counselor



Access to  
Local Resources



Free Nicotine Patches

CONVERSE CON SU MÉDICO SOBRE SU RIESGO DE  
PADECER CÁNCER DE PULMÓN Y SI LAS PRUEBAS  
DETECCIÓN SON APROPIADAS PARA UD.

## EARLY DETECTION SAVES LIVES



THE BEST WAY TO  
REDUCE YOUR RISK OF  
LUNG CANCER IS TO  
**STOP SMOKING**



A 15-MINUTE EXAM COULD SAVE YOUR LIFE

**PAINLESS  
NON-INVASIVE  
NO PREPARATION  
COVERED BY MOST INSURANCE**

INFORMATION PROVIDED BY  
MASS GENERAL  
IMAGING

## LA DETECCIÓN TEMPRANA SALVA VIDAS



LA MEJOR MANERA DE  
REDUCIR EL RIESGO DE  
CÁNCER DE PULMÓN ES  
**DEJAR DE FUMAR**



UN EXAMEN DE 15 MINUTOS PUEDE  
SALVARLE LA VIDA

**SIN DOLOR  
NO INVASIVO  
SIN PREPARACIONES  
LA MAYORÍA DE LOS SEGUROS  
OFRECEN COBERTURA**

INFORMACIÓN SUMINISTRADA POR  
MASS GENERAL  
IMAGING





**DO THINGS DIFFERENTLY**





**OUR WORK IS  
NOT DONE UNTIL  
NO ONE IS  
LEFT BEHIND**





Mass General Brigham

# Center of Excellence in Diversity, Equity and Inclusion in Research

Council on Government Relations (COGR)

**Martha Jones, MA, CIP**

Vice President, Human Research Affairs

Mass General Brigham

February 25, 2021

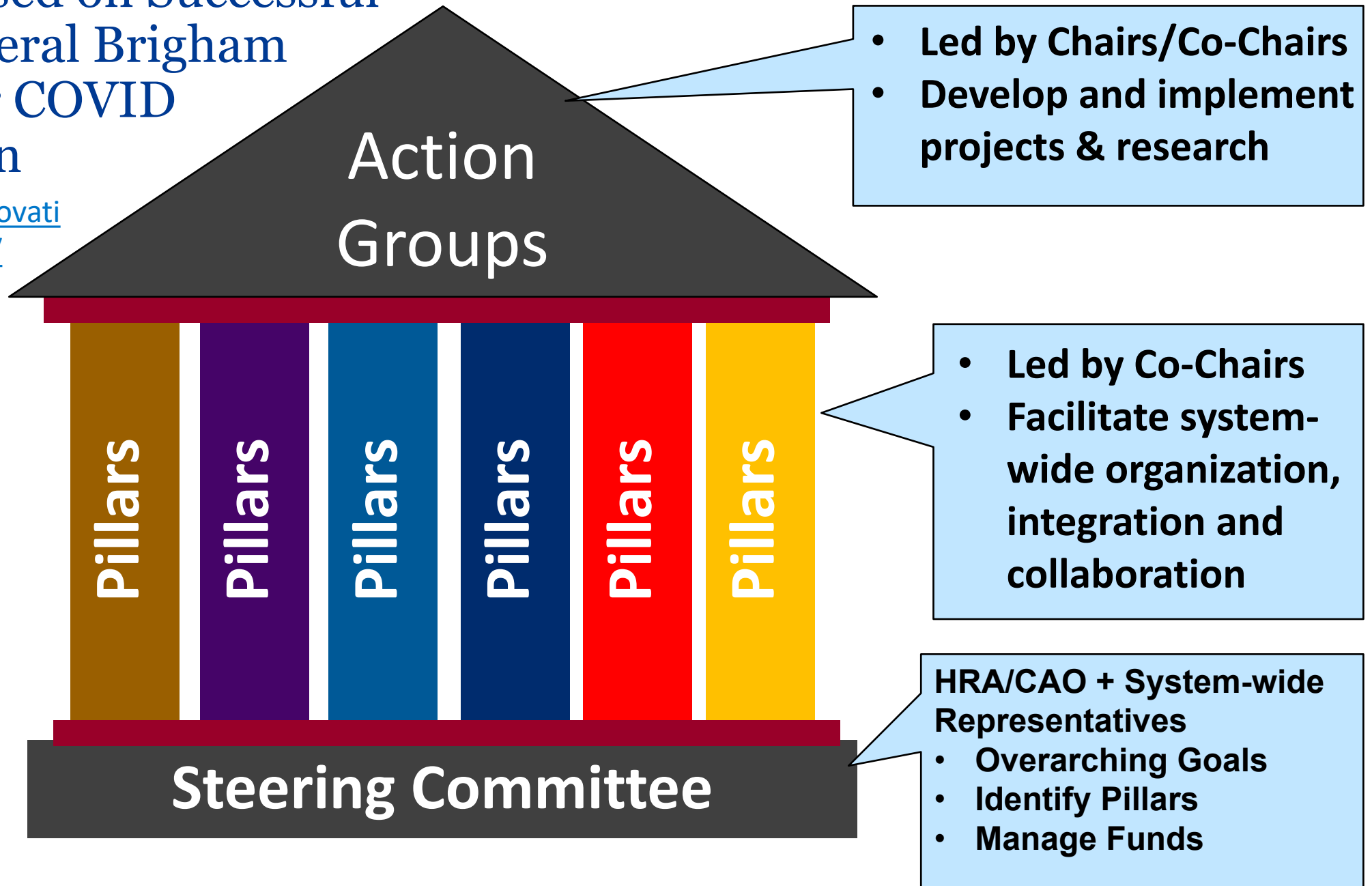
# Mass General Brigham Center of Excellence: Aspirations

- Create a nationally-recognized model
  - Where DEI is the *norm*, not the exception in our research
  - Brings together the innovation, expertise and individual efforts in DEI into a system-wide infrastructure
  - Facilitates actions (initiatives) that result in real and sustainable change in how we conduct research
- Parallels and integrates with clinical initiatives to
  - Remove healthcare disparities
  - Support health care equity goals
  - Improve the lives of our patients and our communities
- Create an infrastructure both locally and nationally for organization, discussion, education, and collaboration



# Model Based on Successful Mass General Brigham Center for COVID Innovation

<https://covidinnovation.partners.org/>





## Research Infrastructure

- Research Review Committees (IRB, SRC, etc)
- Research Staffing
- Partnerships
  - Industry
  - Private
  - Government
  - Community
- Funding
- Data and Analytics

## Research Participant Experience

- Recruitment
- Retention
- Community Engagement
- Connecting to patient experience

## Education

- Conferences
- Symposia/Workshops
- Publications
- Toolkits

## Policy & Regulation

- Local
- State
- Federal ★

## Research Methods & Implementation

- Study Design
- Protocol Development
- Instruments and Measurement
- Analysis Methods

# Bringing “Siloed” Efforts Together



# Key Takeaways

- The DEI Pandemic: needs the same priority and action
- Efforts must have institutional-level coordination, leadership and support
- Lessons from Babar: When your village is burning – Act!





# Task Force on Diversity, Equity & Inclusion in Research

Megan Kasimatis Singleton, JD, MBE, CIP  
Associate Dean, Human Research Protections

February 24, 2021: COGR





WHITE COATS  
BLACK<sup>4</sup> LIVES

## Racial Justice Report Card

2019

### Johns Hopkins University School of Medicine

#### 14. ANTI-RACISM IRB POLICIES

C

There are no specific IRB policies related to race or racism, including no requirements related to how race is defined in research protocols.

# The Charge of The Task Force

Sub-Committee	Assignment
Race/Ethnicity	<ul style="list-style-type: none"><li>• Define a vision for diversity, equity and inclusion in research</li><li>• Identify barriers and facilitators to achieving this vision</li><li>• Outline recommendations to ensure this vision could be achieved</li></ul>
Limited English Proficiency	
Gender	
Disabilities	
Research Across the Lifespan	

**Comprised of over 35 members including community members, faculty, researchers, research staff, IRB members and staff**

# Current Progress/Next Steps

- Full Task Force and subcommittees have met monthly between September- January
- Each subcommittee drafted preliminary recommendations and Task Force members provided feedback
- Recommendations are being compiled into a single report with cross-cutting themes
- Sessions will be held to obtain feedback on recommendations and next steps
- An implementation oversight group will be defined

# Preliminary Considerations

- Assessments have to be comprehensive and continuous
- Small changes can have a great impact
- Sustainable change will require resources

# Mechanisms to get involved

- Help support researchers seeking a forum to discuss barriers to diversity, equity & inclusion in research at your organization
- Consider whether your office/organization's policies and practices support or impede diversity, equity & inclusion in research
- Support the creation of new pathways to enhance diversity, equity and inclusion in research
- Participate in national efforts to improve diversity, equity & inclusion in research

# Q & A

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**Next Session: NSF Director (Guest Speaker) Tomorrow @ 12:30 EST**

Visit us at [www.cogr.edu](http://www.cogr.edu)

Thank You