

# Strategies to Expedite Improvements in Equity, Diversity, and Inclusion in Clinical Trials Participation

2024  
BOSTON

SCT | 45TH  
ANNUAL MEETING

# Speakers



**Suanna Bruinooge**

American Society of  
Clinical Oncology



**Mel Mann**

Survivor and Patient  
Advocate



**Carmen Guerra**

Abramson Cancer  
Center



**Therica Miller**

Mount Sinai, Tisch  
Cancer Institute

# Disclosures

- S. Bruinooge – No relevant disclosures
- M. Mann – No relevant disclosures
- C. Guerra – No relevant disclosures
- T. Miller – No relevant disclosures

# Audience Census

**Please raise your hand if you have the following  
role in research:**

- Patient Advocate/Research Participant
- Research Administrator/Coordinator
- Research Nurse
- Investigator (including Principal, Co-Principal, or Site)
- Biostatistician

# Audience Census

**Please raise your hand if you work in any of the following disease areas:**

Cardiovascular  
Gastrointestinal  
Infectious  
Mental Health

Neurology  
Oncology  
Respiratory  
Other

# Session Outline

1. Cancer Survivor and Patient Advocate Perspective
  - Mel Mann, MBA, M.Ed
2. Resources for Research Sites to Improve Equity, Diversity, and Inclusion (EDI)
  - Suanna Bruinooge, MPH
3. Cancer Centers and Expectations of Federal Agencies
  - Carmen Guerra, MD, MSCE, FACP
4. Addressing Barriers to Accessing Clinical Trials
  - Therica Miller, MBA, CCRP

# **Cancer Survivor and Patient Advocate Perspective**

**Mel Mann, MBA, M.Ed**





**SOLDIER IN URGENT NEED OF A MARROW DONOR!**



Melvin has dreams for a successful career in the US Army. Those dreams as well as his life may soon end if a marrow donor cannot be found. He has CML, a type of Leukemia. His best hope for a match would be someone of African American heritage. All it takes is a simple blood test to tell if you can help. Please register to give the "Gift of Life!"

Blood testing to enter the National Registry is provided free of charge.

**SELFRIDGE ANGB  
and the  
DoD MARROW DONOR CENTER  
MARROW DONOR DRIVE**

**ALL ACTIVE DUTY MILITARY, ACTIVE DUTY DEPENDENTS, DEPARTMENT OF DEFENSE CIVIL SERVICE EMPLOYEES, NATIONAL GUARD & DRILLING RESERVE PERSONNEL  
AGES 18 TO 55 ARE ELIGIBLE**

**WHEN : 23 APRIL 1995 from 1200-1800 hours  
PLACE: BUILDING 780, ROOM 18**

**Retired major needs bone marrow transplant**  
**Former TRADOC officer fights for life**

BY CONNIE SMALLS  
COLUMBUS, MISSISSIPPI

Retired Maj. Melvin Mann, former executive officer for DCSDB, TRADOC, between May 91-94, is in urgent need of a bone marrow donor.

Mann, temporarily retired from active duty, discovered this past January that he had CML, a type of leukemia. Doctors say his only hope to survive the disease is a bone marrow transplant.

"My sister wanted to be a donor, but she didn't match," he said. "We know it was only a 25 percent chance that she would."

His best hope for a match would be someone of African-American heritage. "Statistics show that out of the 1.8 million donors on the national and international registries, 300,000 are sensitive and out of the sensitives only 100,000 are African-American," he said.

Throughout Department of Defense, efforts are underway to help an estimated 16,000 American children and adults victims each year with fatal blood diseases such as leukemia. Of these, there are approximately 500 active-duty military and dependents currently in need of unrelated bone marrow transplants.

**Man on mission not to give up**

**MARROW DONOR NEEDED NOW!**

Melvin has a successful career in the Army and a wonderful wife and 6 year old daughter. His life however may soon end if a marrow donor cannot be found. Melvin has CML, a type of Leukemia. His best hope for a match could be someone of African American heritage. All it takes is a simple blood test to tell if you can help. Please take a moment and consider the

**Mississippi man searching for marrow donor**

**Bone marrow drive may save man's life**

TO MRS. DEMMING AND MR. MANN WE, THE STAFF AND ALL MEMBERS OF SOUTH COLUMBUS BOYS CLUB, HAVE RELATIONS OF SUPPORT.

**Major sees hope in Pentagon drive**

by Cyndi Stiel  
special to the Pentagongram

How would you feel if you gave a life-saving gift this holiday?

How would the recipient feel?

Retired Maj. Melvin Mann is raising out of me. This 30-year-old husband and father has CML, a type of leukemia, and is in dire need of a life-saving gift.

Mann, temporarily retired from his 15-year successful career in the Army, is one of the more than 16,000 Americans each year who are diagnosed with leukemia, aplastic anemia or 60 other fatal diseases. For many, their only chance for survival is a bone-marrow transplant.

"My sister and other family members tested to be donors, but no one matched," he said. "We know it was only a 25-percent chance that they could." But then, Mann added, "But my one hope is a possible match for someone else, and I'm excited about that."

Mann, an African American, said his best hope for finding a matched donor lies in a member of his own race. "I do encourage all races to come out and donate, because there are people from all races in need of a bone-marrow transplant," he said. "People can give Christmas gifts without spending any money."

"The first step toward becoming a marrow donor involves a simple blood test -- often taken during bone-marrow screening drives like the one that will occur at the Pentagon on Christmas, a week before Christmas."

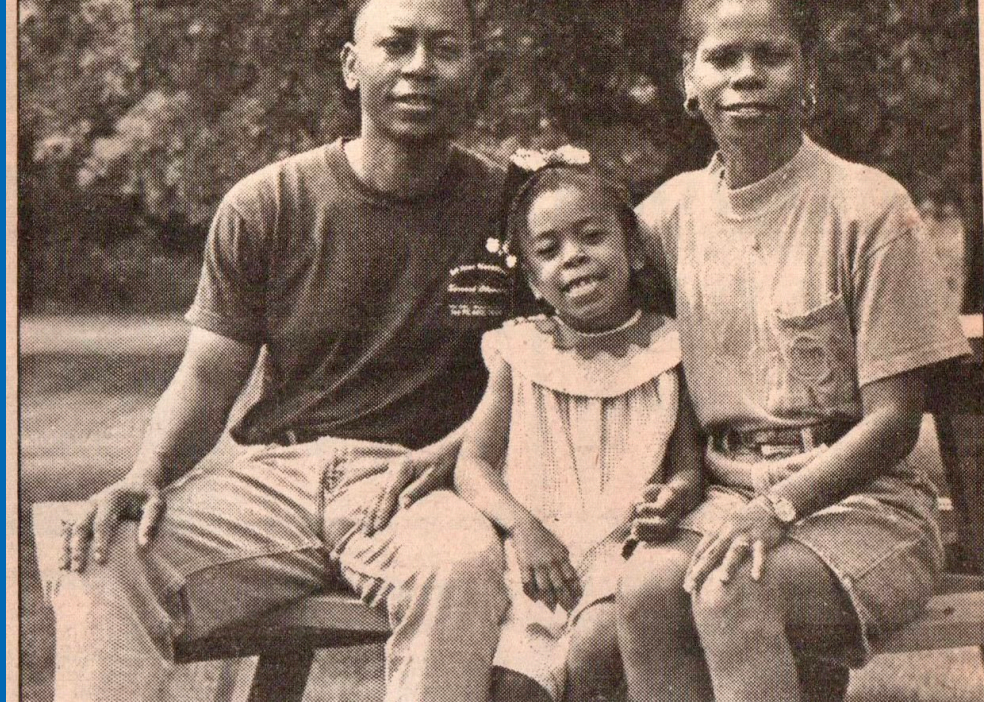
Volunteer donors must be between the ages of 18 and 55 and in good general health. The process is as follows:

- You give a small amount of blood and consent to be entered in the marrow donor registry.
- Your blood is "HLA typed." This determines the type of marrow you have.
- Your HLA type goes into a database.
- If you are a preliminary match, additional

**Paraglide**  
Life saving marrow donors sought



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# Tyrosine Kinase Inhibitors (TKIs) For CML Treatment

*(CML TKIs are taken orally)*

**Imatinib**  
1<sup>st</sup> Generation  
FDA Approved 2001  
(Treats 12 Different Cancers)

**Dasatinib**  
2<sup>nd</sup> Generation  
FDA Approved 2006

**Nilotinib**  
2<sup>nd</sup> Generation  
FDA Approved 2007

**Bosutinib**  
3<sup>rd</sup> Generation  
FDA Approved 2013

**Ponatinib**  
3<sup>rd</sup> Generation  
T325I Mutation  
FDA Approved 2012

**Asciminib**  
3<sup>rd</sup> Generation  
T315 Mutation  
FDA Approved 2021

**There are 80 FDA kinase inhibitors and seven of these drugs were approved in 2023. Here is a list of a number of diseases they treat.**

**Neoplasms**

**Atopic dermatitis**

**Rheumatoid Arthritis**

**Psoriasis**

**Alopecia Areata**

**Ulcerative Colitis**

**HER2 – Positive Breast Cancer**

**Metastatic Colorectal Cancer**

**Myelofibrosis**

**Mantle Cell Lymphoma**

**Chronic Lymphocytic Leukemia**

**ROS1- Positive Lung Cancer**

**Colon Cancer**

**Kidney Cancer**

**Melanoma**

**Chronic Myeloid Leukemia**

**Head and Neck Cancer**

**Macular Degeneration**

**Hepatocellular Carcinoma**

**Pancreatic Cancer**

**Thyroid Cancer**

**Gastrointestinal Stromal Tumors**

**Alopecia Areata**

# Resources for Patient Support

## Disease-Specific Patient Organizations

- Leukemia & Lymphoma Society financial support

## Patient Advocate Foundation

- Financial aid for people with chronic, life threatening, and debilitating illnesses.

## American Cancer Society

- Lodging, navigation support, transportation

## Lazarex Cancer Foundation

- Patient Trial Navigation and Financial Assistance (transportation & lodging)

## Cancer Care

- Costs for transportation and childcare

## Patient Access Network Foundation

- Help underinsured people with life-threatening, chronic, and rare diseases by assisting with their out-of-pocket costs

## Health Well Foundation

- Help with copays, premiums, deductibles and out-of-pocket expenses

## Equitable Access to Clinical Trials Project

- Tools for research sites to assess participant needs and engage sponsors for funding.

## Angel Flight

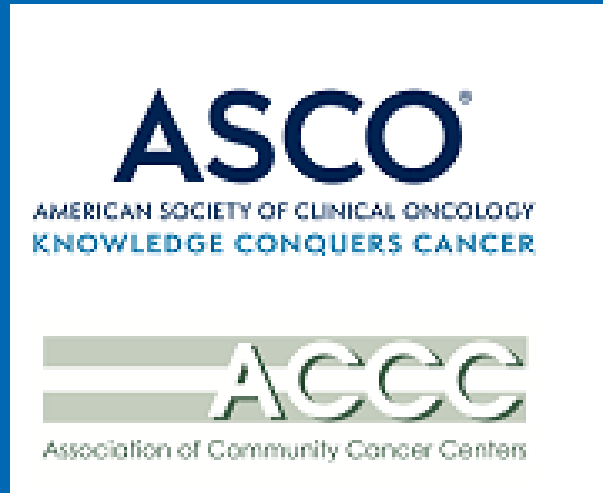
- Flight assistance for patients needing care in Oklahoma, Texas, Arkansas, Missouri, & Kansas.

## Cancer Financial Assistance Coalition Database – [cancerfac.org](http://cancerfac.org)

# Resources for Research Sites to Improve EDI

**Suanna Bruinooge, MPH**

# Initiative to Increase Racial & Ethnic Diversity in Clinical Trials



## Improve Equity, Diversity, and Inclusion in Your Cancer Clinical Trials



### READ

Research Statement on  
Diversifying Clinical Trials



### TAKE

EDI Research Site  
Self-Assessment



### COMPLETE

*Just ASK*<sup>™</sup>  
Implicit Bias Training Program

# Improving Racial and Ethnic Diversity in Cancer Clinical Trials

## An ASCO-ACCC Research Statement

Actions to engage all research stakeholders and ensure every individual with cancer has an opportunity to participate in a clinical trial.

### The recommendations cover:

- Access to Clinical Trials
- Equity-Focused Trial Design
- Partnerships with Patient Orgs & Communities
- Investment in Equity, Diversity, and Inclusion
- Education and Training
- Sharing Data on Trial Participants and Successful Strategies



Learn more and access resources via:  
[www.asco.org/asco-accc](http://www.asco.org/asco-accc)

# Research Site Self-Assessment

## ASCO-ACCC Equity, Diversity, and Inclusion Research Site Self-Assessment

Enables research sites to identify opportunities to improve equity, diversity, and inclusion in clinical research while doing an internal review of their programs, policies, procedures.

- ✓ Gain insights to improve programs, policies, procedures, and mitigate disparities
- ✓ Identify evidence-based strategies and resources
- ✓ Create and/or maintain a culture of continuous quality improvement



# Implicit Bias Training Program

*Just ASK™* Increasing Diversity in Cancer Clinical Research: An ACCC-ASCO Training Program

Enables clinicians and staff to assess and mitigate biases regarding who is screened for and offered clinical trials.

- Curriculum-based training program enables research and care teams to address implicit bias
- Five interactive modules can be completed independently in about 60-90 minutes
- A companion facilitators' guide is available to help sites continue the conversation with the larger research team after taking the training

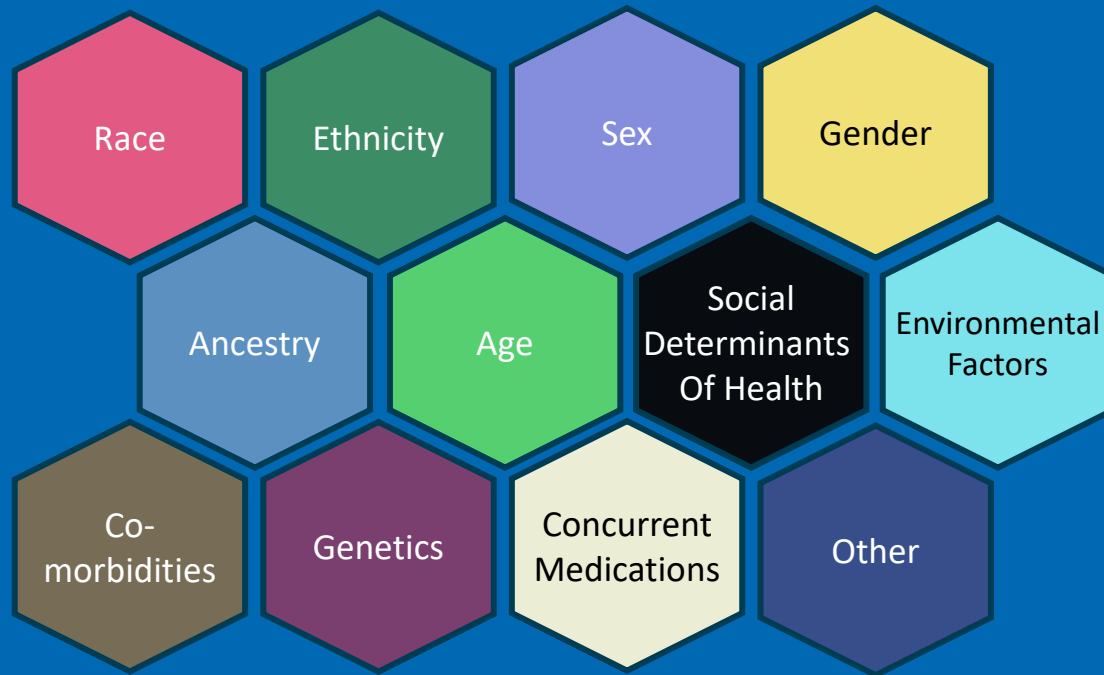
# Broadening Clinical Trial Eligibility Criteria

**Problem: Eligibility criteria are restrictive and limit trial access.**

- Eligibility criteria should be broad to improve access and inclusion
  - Cultural change required to start with proposition of inclusion.
  - Example: Historically, patients who were HIV+ were *routinely* not included.
- ASCO and Friends of Cancer Research collaborated with FDA and NCI
  - Recommendations for expanded eligibility criteria in 2017 and 2021
- FDA guidance documents and NCI protocol template changes are helping move the needle

# Diversity exists across many dimensions

Diversity requires a broad definition



Understanding diversity requires an appreciation of intersectionality: dimensions of diversity are not independent variables.

# Call to Action to Advance Patient-Focused and Decentralized Trials

Enable patients to receive trial related testing and care near or in their homes, rather than requiring travel to major research institutions



[doi.org/10.1002/cncr.35145](https://doi.org/10.1002/cncr.35145)

FDA Form 1572

- Clarity with FDA Form 1572 requirements to ensure consistent interpretation

Local/Remote Care

- Routine acceptance of local/remote patient care and testing

Collaborations

- Foster partnerships to increase patient and local clinician access to trials

# Clinical Trial Modernization Act (H.R. 8412)

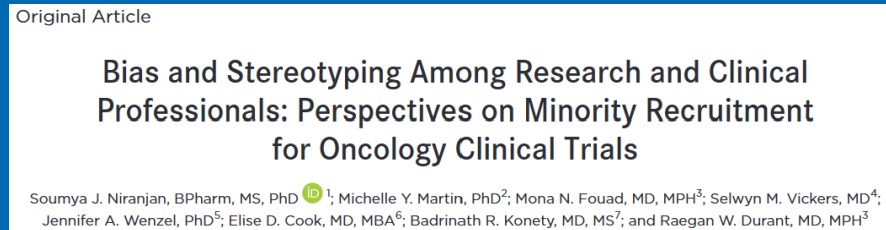
- Introduced by Representatives Raul Ruiz, MD (D-CA) and Larry Bucshon, MD (R-IN)
- Allow sponsors to financially support participants for medical and non-medical costs
- Allow sponsors to provide participants with digital health technology necessary for participation at no cost
- Ensure that support from sponsors to participants is not subject to taxation nor counted against income limitations for safety net programs
- Allow the Department of Health and Human Services to issue grants to support community education, outreach, and recruitment

# **Cancer Centers and Expectations of Federal Agencies**

**Carmen Guerra, MD, MSCE, FACP**

# Role of Unconscious Bias

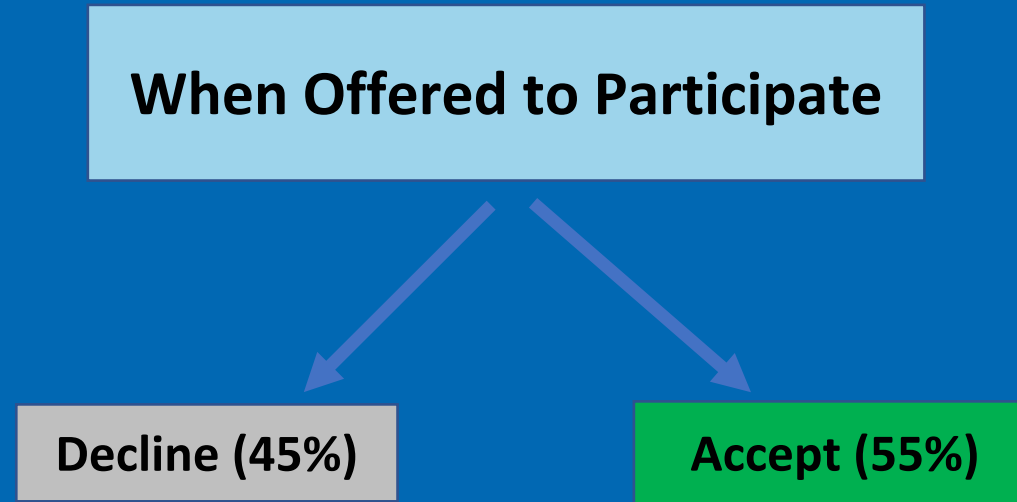
- 91 qualitative interviews were conducted at 5 U.S. cancer centers among 4 stakeholder groups: 1) cancer center leaders; 2) PIs; 3) referring clinicians; and 4) research staff.



- 5 themes emerged about perceptions of minority participants:
  - **Challenging**
  - **Not ideal study candidates**
  - **Are not as altruistic**
  - **Legacy of mistreatment**
  - **Perceptions led to withholding clinical trial opportunities**

Niranjani, Soumya J et al. Bias and stereotyping among research and clinical professionals: Perspectives on minority recruitment for oncology clinical trials. *Cancer*. 2020; 126(9): 1958-68.

# “When Offered to Participate”



- There was **no statistically significant difference in participation rates by race.**
- Underrepresented minority patients are not less likely to agree to participate in treatment trials

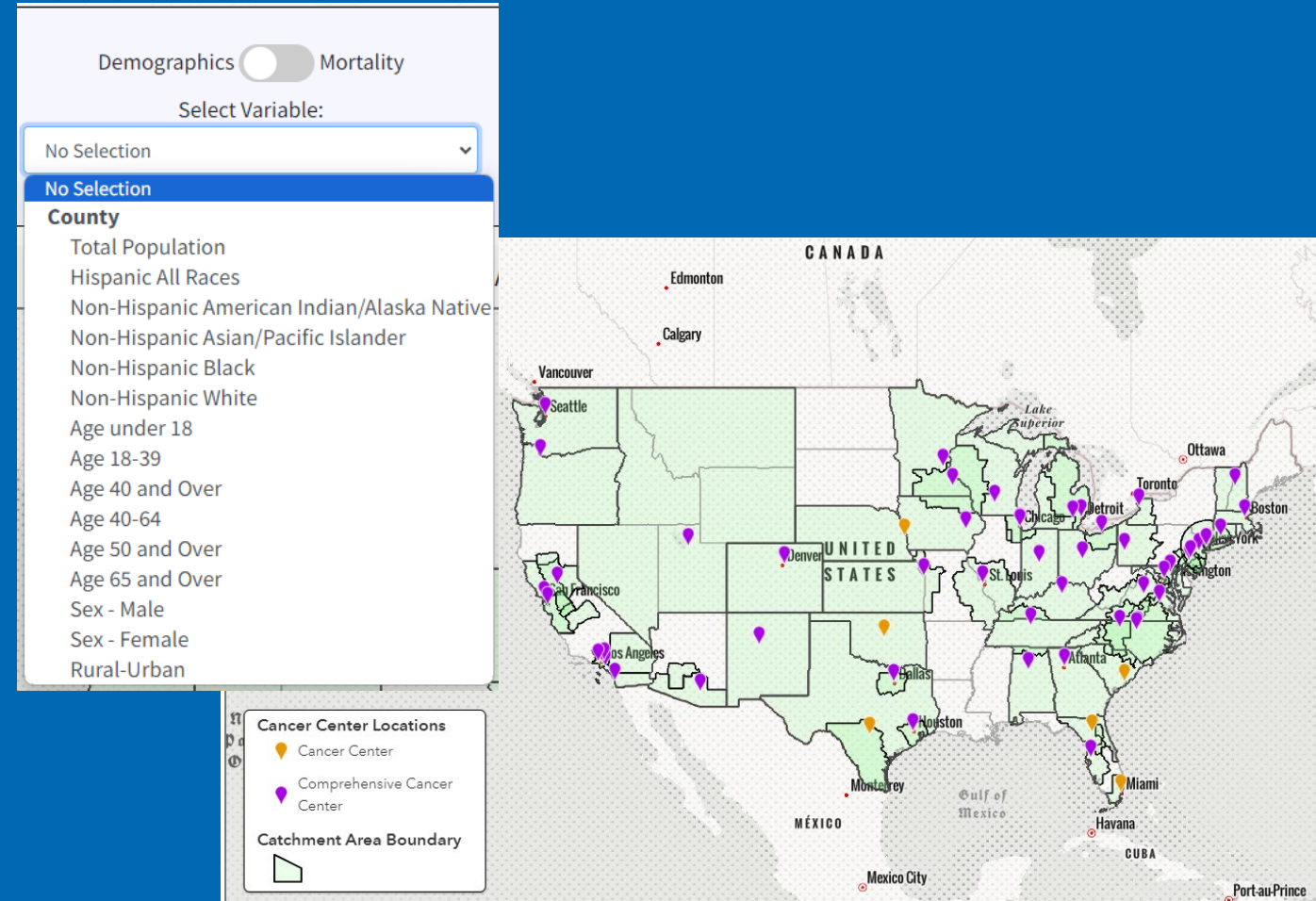
	White	Black	Hispanic	Asian
Treatment Trials (n=30) Participation Rates	53.4%	57.6%	64.9%	61.7%

# Cancer Center Resources

- Community outreach and engagement
  - Establish partnerships to co-create initiatives and programs that engage & disrupt segregated care
  - Community Advisory Board
- Translation
  - IRB short forms, My Accessible Real-Time Trusted Interpreter (MARTTI)
- Financial reimbursement of clinical trial related out-of-pocket costs
  - Copays (Patient Advocate Foundation)
  - Travel and lodging (Lazarex Cancer Foundation, American Cancer Society, Ride Health)

# Catchment Areas of NCI-Designated Cancer Centers

- Web-based visualization tool for the geographically defined catchment areas of NCI-designated Cancer Centers.
- The 'catchment area' refers to the self-defined geographic area that each NCI-designated Cancer Center serves or intends to serve in the research it conducts, the communities it engages, and the outreach it performs.

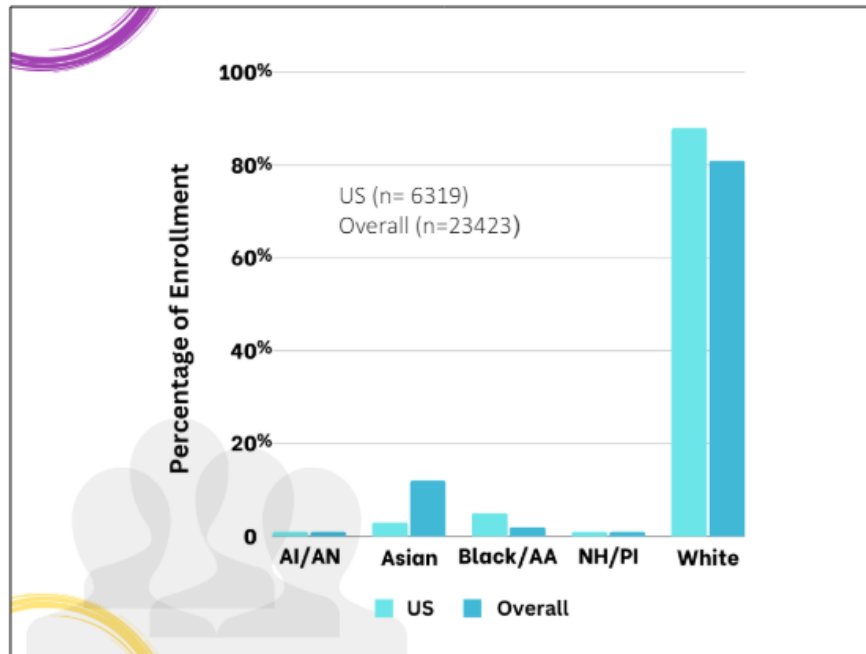


# FDA Analysis of Trial Participants

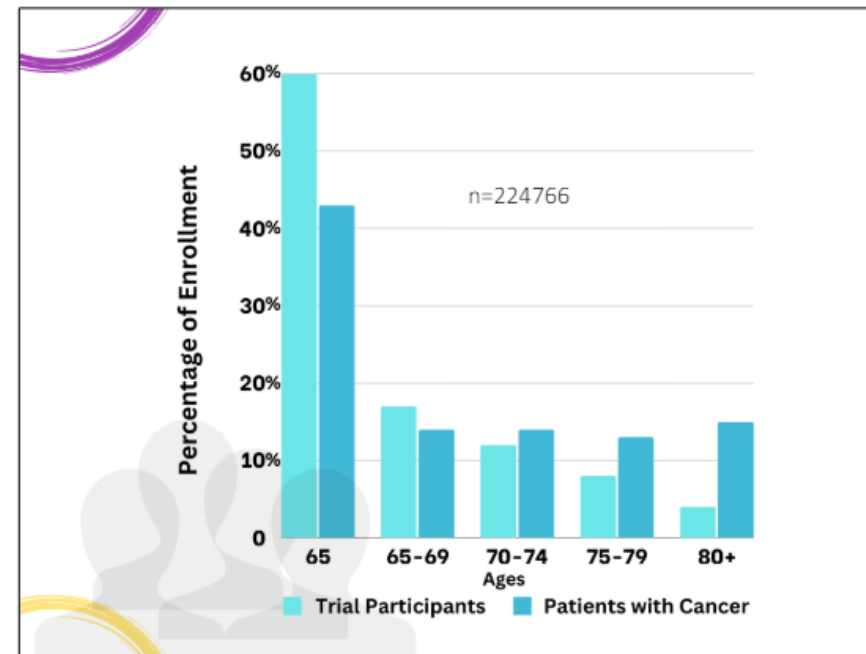


## Participants in Oncology Clinical Trials Race & Older Age

Racial Composition of Participants Enrolled in Trials of  
New Drugs Approved from 2011-2017<sup>1</sup>



Older Adult Representation in Oncology Drug Trials<sup>2</sup>

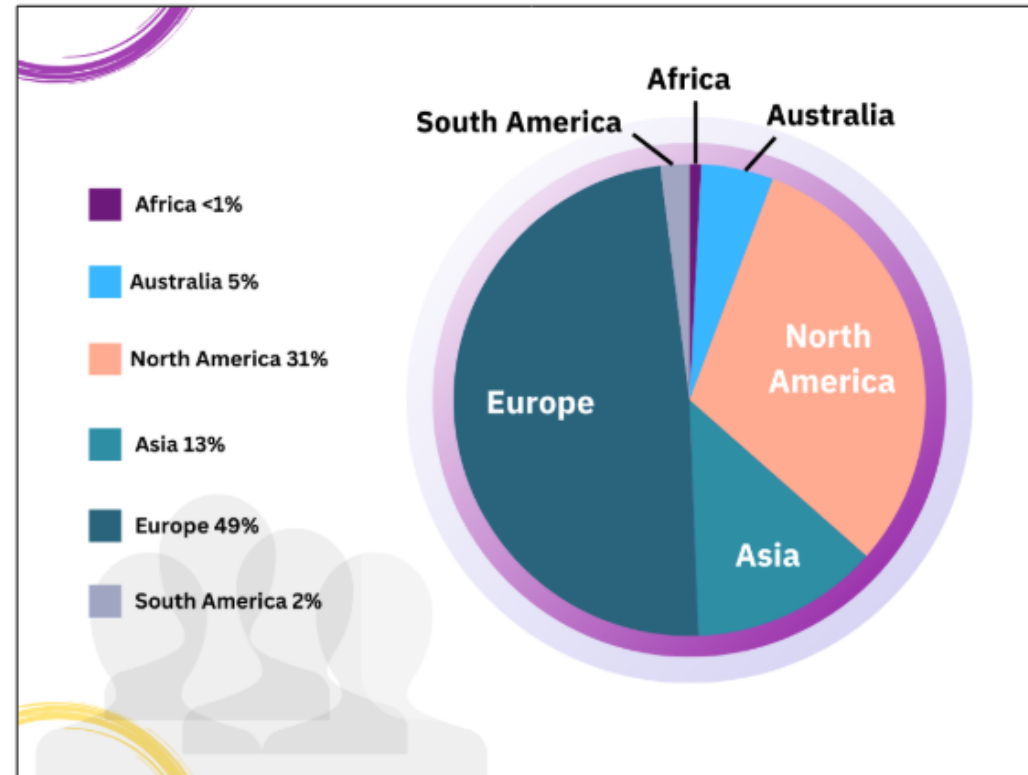


1. Fashoyin-Aje et al. Unpublished FDA analysis of NME approved 2011- 2017

2. Singh et al, ASCO Annual Meeting, 2017

# FDA Analysis of Trial Participant Location

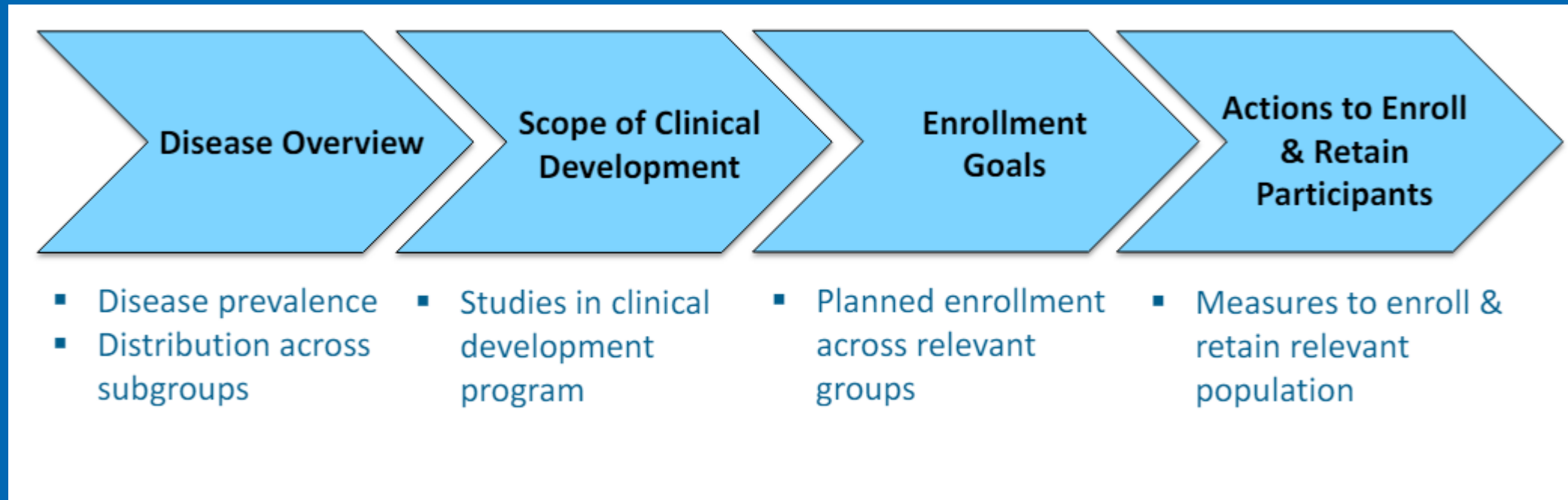
## Geographical Distribution of Participants Enrolled in Trials of New Oncology Drugs Approved from 2011-2017<sup>1</sup>



1. Fashoyin-Aje et al. Unpublished FDA analysis of NME approved 2011- 2017.

# FDA *Draft* Diversity Plan Guidance

Issued April 2022



Lola Fashoyin-Aje, MD, MPH, Deputy Director, DOIII  
Associate Director- Science and Policy to Address Health Disparities

Guidance available at [www.fda.gov/media/157635/download](http://www.fda.gov/media/157635/download)

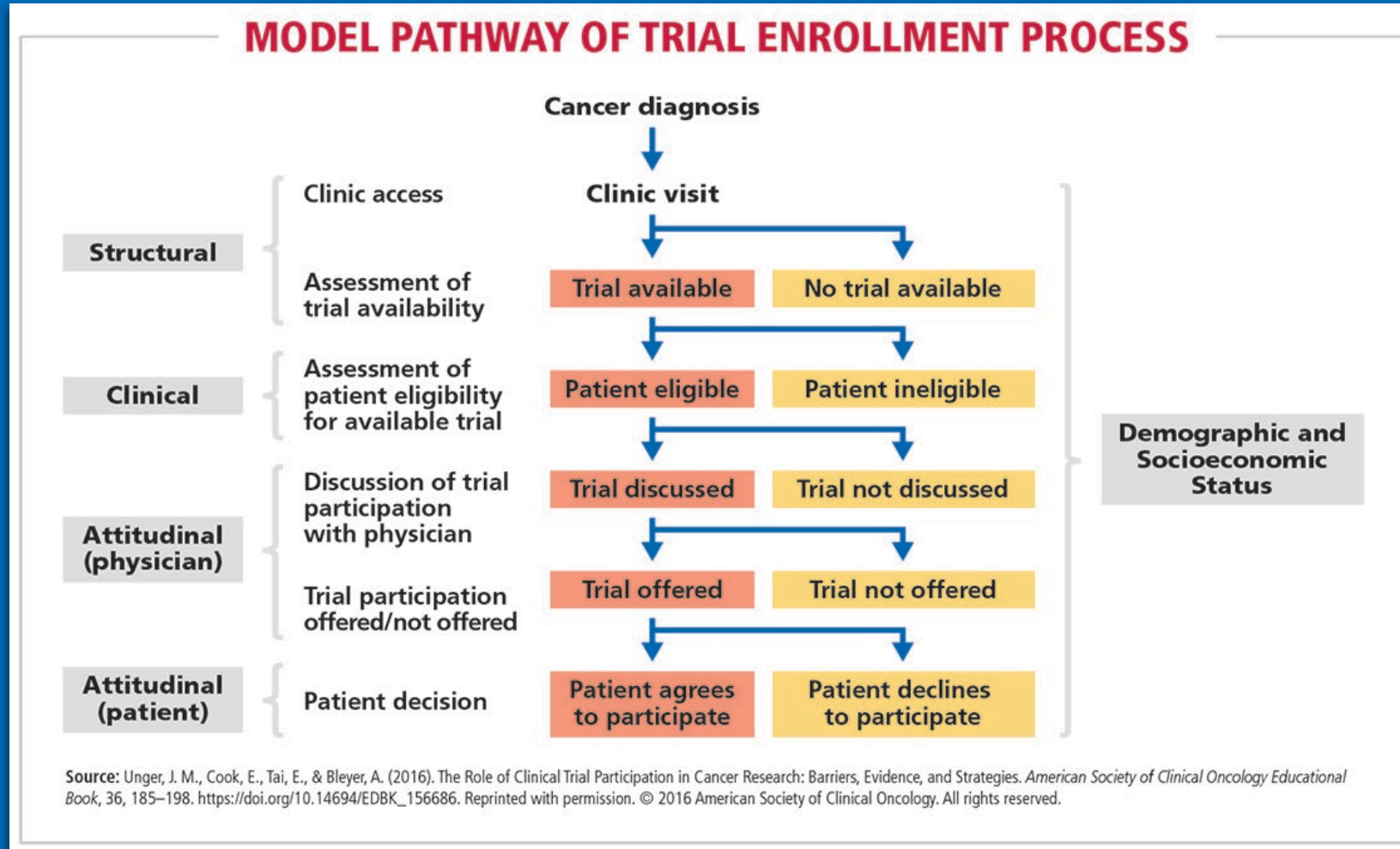
# Addressing Barriers to Accessing Clinical Trials

**Therica Miller, MBA, CCRP**

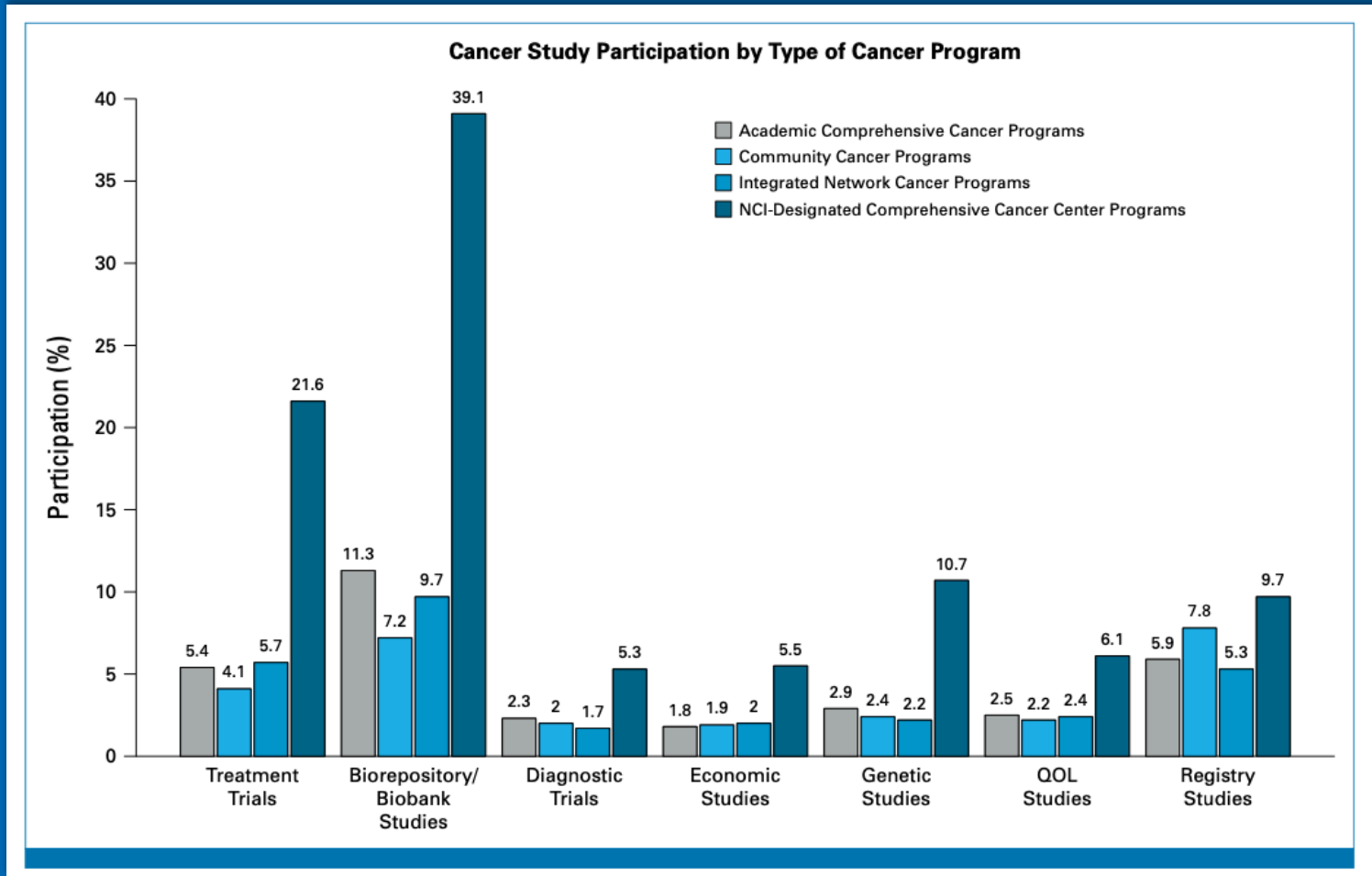
# Major Factors Influencing Patient Participation?

1. Buy-In and Trust
2. Identification of relevant trial
3. Eligibility criteria
4. Prior treatments
5. Invitation to participate
6. Trial requirements (e.g., visit frequency, testing, etc.)
7. Health insurance
8. Out-of-pocket costs and expenses
9. Travel/transportation
10. Caregiver/Community support

# Multi-Factorial Challenges to Participation



# Expand Research Capacity & Infrastructure



*Participation in treatment trials is 5x greater at NCI Designated centers*

- Virtual clinical trials offices
- Decentralized /mobile trial staff
- Just-in-time programs
- Leverage EMRs for data exchange

# Modernizing Clinical Trial Design

## Barrier: Eligibility Criteria and Comorbidities

- [Treated/stable brain metastases](#)
- [New/progressive brain metastases for early phase trials](#)
- [New/progressive brain metastases for later phase trials](#)
- [Patients younger than age 18 years](#)
- [Patients with HIV, HBV, and HCV infection](#)
- [Prior/concurrent malignancies](#)
- [Organ function: cardiac, liver, and kidney](#)
- [Washout periods](#)
- [Concomitant medications](#)
- [Prior therapies](#)
- [Laboratory reference ranges and test intervals](#)
- [Performance status](#)
- [Psychiatric Illness/Social Situations](#)

**Adaptive Trial Designs:** Advocate for and design clinical trials with broader eligibility criteria to include patients with common comorbidities, reflecting the real-world patient population.

**Subgroup Analysis:** Design trials to include subgroup analyses that can provide valuable data on how treatments work in patients with different comorbidities.

**Patient-Centered Protocols:** Involve patients in the design phase of clinical trials to create more inclusive protocols that consider the needs and conditions of older adults.

### 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

THE NEW ENGLAND JOURNAL of MEDICINE

### MEDICINE AND SOCIETY

Debra Malina, Ph.D., Editor

### Hidden in Plain Sight — Reconsidering the Use of Race Correction in Clinical Algorithms

Darshali A. Vyas, M.D., Leo G. Eisenstein, M.D., and David S. Jones, M.D., Ph.D.

ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY

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## Clinical Trial Eligibility Criteria

Broadening Eligibility Criteria to Make Clinical Trials More Representative

# Taking Research to Patients

## Barrier: Limited Access to Trial Sites



The NEW ENGLAND  
JOURNAL of MEDICINE

ORIGINAL ARTICLE f X in ✉

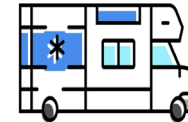
### A Cluster-Randomized Trial of Blood-Pressure Reduction in Black Barbershops

**Authors:** Ronald G. Victor, M.D., Kathleen Lynch, Pharm.D., Ning Li, Ph.D., Ciantel Blyler, Pharm.D., Eric Muhammad, B.A., Joel Handler, M.D., Jeffrey Brettler, M.D., [+5](#), and Robert M. Elashoff, Ph.D. [Author Info & Affiliations](#)

Published March 12, 2018 | N Engl J Med 2018;378:1291-1301 | DOI: 10.1056/NEJMoa1717250  
**VOL. 378 NO. 14**



**Decentralized Trial Elements:** Implement decentralized or hybrid trial models that allow patients to participate from their homes or local healthcare facilities.



**Mobile Clinics:** Use mobile clinics to bring trial services directly to patients in remote areas, reducing the need for long-distance travel.

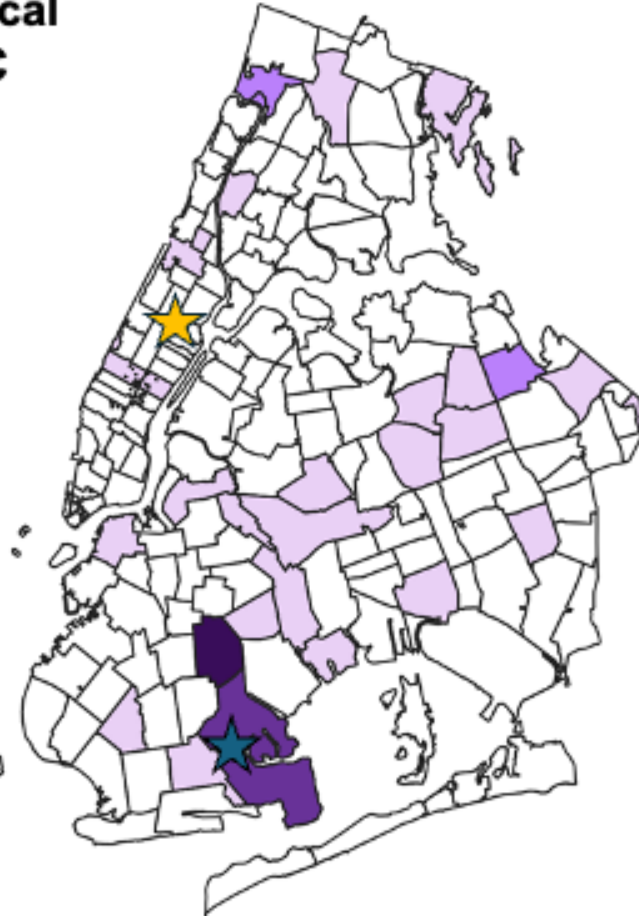
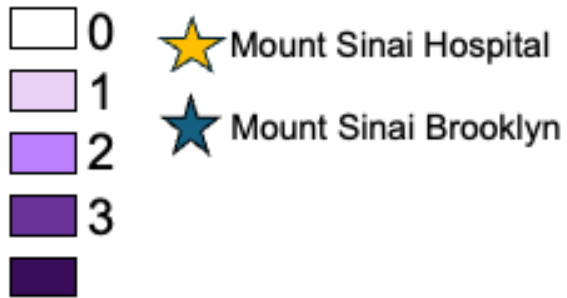


**Local Partnerships:** Partner with local healthcare providers and clinics to act as satellite sites for larger clinical trials, expanding access without significant travel burdens.

# Hybrid Clinical Trial Model

Barrier: Time and Financial Toxicity

## 2022 Multiple Myeloma Clinical Trial Enrollment Across NYC



"If there were equivalent facility somewhere in North Brooklyn, that would be a tremendous assistance... as the major cancer treatment hospitals are all in Manhattan which makes it very difficult for anybody in the outer boroughs to get to them."

Mapping the data helped to illustrate the need for clinical trial site expansion to better serve our patient population and to facilitate minority access to trials.

Enrollment among Black Patients in Multiple Myeloma Trials at Brooklyn Site

2022: **80%**

2023: **85%**

# Understanding Provider Challenges

## Barrier: Invitation to Participate

Row Labels		No - Not appropriate for this patient	No - Patient ineligible for clinical tri...	No available study	Yes - Declined participation	Yes - Enrolled on clinical trial	Yes - Screened, but found to be ineligib...	Grand Total
Breast	25.00%	4.17%	3.47%	66.67%	0.69%	0.00%	0.00%	100.00%
Gastrointestinal	18.08%	3.05%	1.64%	74.65%	1.64%	0.94%	0.00%	100.00%
Gynecological	27.51%	3.17%	2.65%	62.96%	1.59%	2.12%	0.00%	100.00%
Head & Neck	10.87%	2.17%	8.70%	63.04%	4.35%	10.87%	0.00%	100.00%
Hodgkin Lymphoma	50.00%	0.00%	0.00%	50.00%	0.00%	0.00%	0.00%	100.00%
Leukemia	20.41%	11.22%	9.18%	58.16%	0.00%	1.02%	0.00%	100.00%
Myeloma	34.92%	8.87%	8.05%	46.66%	0.95%	0.00%	0.55%	100.00%
Neurological	12.50%	6.25%	6.25%	50.00%	12.50%	12.50%	0.00%	100.00%
Non-Hodgkin Lymphoma	21.74%	4.35%	0.00%	73.91%	0.00%	0.00%	0.00%	100.00%
Other & Unspecified Tumor Sites	23.08%	2.56%	7.69%	64.10%	2.56%	0.00%	0.00%	100.00%
Other Hematological	29.41%	0.00%	11.76%	52.94%	5.88%	0.00%	0.00%	100.00%
Skin	22.50%	3.75%	6.25%	61.25%	0.00%	3.75%	2.50%	100.00%
Thoracic	24.73%	2.15%	1.08%	70.97%	1.08%	0.00%	0.00%	100.00%
Treatment & Side Effects	21.50%	4.50%	6.00%	63.00%	2.50%	2.50%	0.00%	100.00%
Urological	16.90%	2.82%	12.68%	56.34%	7.75%	2.11%	1.41%	100.00%
#N/A	20.16%	6.20%	6.72%	60.96%	1.93%	2.86%	1.17%	100.00%
<b>Grand Total</b>	<b>23.26%</b>	<b>5.78%</b>	<b>6.21%</b>	<b>60.24%</b>	<b>1.87%</b>	<b>1.92%</b>	<b>0.71%</b>	<b>100.00%</b>

*When asked “was a clinical trial discussed with this patient”*

*Most providers indicated “no available study”*

# Patient-Centric Approach to Each Study



# Policies and Procedures

## TABLE OF CONTENTS

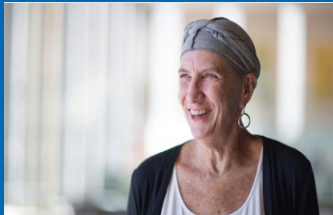
Site Management Plan .....	1
Vision and Mission Statement .....	5
Purpose and Scope .....	5
Introduction .....	5
Diversity Statement .....	5
Leadership and Governance .....	6
Executive Leadership .....	6
Core Research Faculty .....	6
Disease Focus Groups (DFG) .....	7
Clinical Research Support Unit .....	7
Policies and Procedures .....	7
Facility Overview .....	8
Inpatient Locations .....	8
Outpatient Locations .....	9
Ancillary Services .....	10
Clinical Laboratory Services .....	10
Radiology Services .....	11
Cardiology Services .....	12
Radiation Therapy Services .....	13
Surgery Services .....	13
Ophthalmology Services .....	14
Dermatology Services .....	14
Cellular Therapy Services .....	14
Apheresis Services .....	14
Research Laboratory .....	14
Biospecimen Management .....	15
Investigational Drug Services (IDS) Pharmacy .....	16
Investigational Product Shipment and Transport .....	16
Investigational Product Handling .....	18
Inventory Management and Monitoring .....	18

Protocol Activation .....	19
Site Selection .....	19
Protocol Activation Process .....	19
Protocol Review Timeline .....	20
Communication Expectations .....	21
Fast Track .....	22
Regulatory Affairs .....	22
Protocol Review and Monitoring System .....	22
Institutional Review Board and Privacy Board .....	24
Ancillary Oversight and Review Committees .....	26
Research Credentialing .....	27
Central Regulatory Files .....	27
Regulatory and Essential Documents Storage .....	28
Electronic Signatures .....	28
Clinical Trial Agreements .....	29
Site Fees .....	29
Coverage analysis .....	29
Budgeting practices .....	30
Systems .....	31
Study Oversight .....	33
Principal Investigator Oversight .....	33
Protocol Training .....	34
Training Documentation .....	34
Central Registration .....	35
Study Safety Information .....	35
Source Documentation .....	35
Informed Consent .....	36
Interpreter Services .....	36
Case Report Forms .....	37
Record Retention .....	37
Long Term Storage of Research Records .....	37
Monitoring .....	38
Monitoring Visits .....	38
Access to Source Documentation .....	38

Audits and Inspections .....	39
Appendices .....	39
Appendix I: Closed System Transfer Devices (CSTDs) and Ancillary Supply List .....	40
Appendix II: The Tisch Cancer Institute, Clinical Research Support Unit Memorandum – Source Data/Document Location Forms, June 2023 .....	48
Appendix III: Tisch Cancer Institute Clinical Research Support Unit Key Contacts .....	51

60 page  
document outlining  
oversight plan

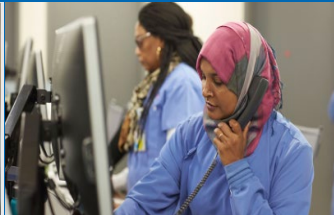
# Bridging Academic-Community Partnerships



## Valley-Mount Sinai Comprehensive Cancer Care

By establishing new clinical programs and services, we are continually increasing treatment options for patients.

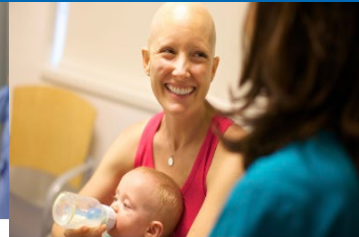
[Learn More](#)



## Advanced Radiation Center of New York (ARC) (A Division of Integrated Medical Professionals, PLLC)

Our teams are highly skilled in providing the newest therapies and technologies in radiation oncology.

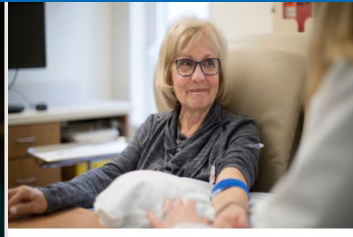
[Learn More](#)



## Summit-CityMD

Our teams provide the finest surgical, diagnostic, and therapeutic ancillary services for cancer patients in New Jersey.

[Learn More](#)



## New York Cancer & Blood Specialists

As a premier network of community oncology treatment centers, we deliver leading-edge care to Long Island patients.

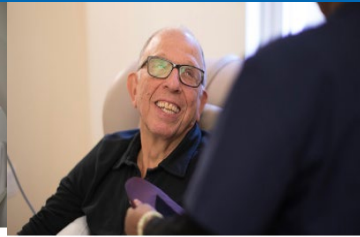
[Learn More](#)



## The Brooklyn Hospital Center

To better serve the residents of northern Brooklyn and beyond, we are expanding our range of specialized services.

[Learn More](#)



## Holy Name Medical Center

To provide the best care to northern New Jersey, we are bringing patients convenient access to the newest therapies.

[Learn More](#)



## BronxCare-Mount Sinai Comprehensive Cancer Care

We are enhancing patient care by establishing new programs and services in oncology and other disciplines.

[Learn More](#)

# Which Factors are Priorities to Address?

1. Buy-In and Trust
2. Identification of relevant trial
3. Eligibility criteria
4. Prior treatments
5. Invitation to participate
6. Trial requirements (e.g., visit frequency, testing, etc.)
7. Health insurance
8. Out-of-pocket costs and expenses
9. Travel/transportation
10. Caregiver/community support

# Solutions to Employ

- **Trial Design**

- Incorporate broadened eligibility criteria
- Flexibilities to alleviate patient burden – accommodating schedules, telehealth, decentralized testing and scans

- **Community Engagement**

- Connections to establish trust and recognize cultural differences
- Extends beyond research to address health continuum

- **Embedding Trials in Routine Workflows**

- Identify patients and trials in EHRs
- Following routine clinical care timing and treatments in controls

# Discussion