

Wednesdays 11AM -12noon ET



**LEANING IN: A WEBINAR SERIES** 

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The MRCT Center is supported by voluntary contributions (www.MRCTCenter.org) and grants.





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#### **LEANING IN: A WEBINAR SERIES**

**Recording available** Community Awareness, Access, Knowledge

October 28, 2020 Workforce Development

**November 18, 2020** Study Design, Eligibility, Site Selection & Feasibility

**December 9, 2020** Study Conduct (Recruitment, Retention)

**January 13, 2021** Data Standards and Analysis

**January 27, 2021** Stakeholder Roles and Responsibilities

**February 10, 2021** Role of Data in Diversity: Genetics & Real World Data



## Today's topic

#### **WORKFORCE DEVELOPMENT**

October 28, 2020 11AM -12noon ET



Luther T. Clark, MD Moderator Deputy Chief Patient Officer, Merck



Sarah A. White, MPH
Moderator
Executive Director,
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Racquel W. Bruton Guest Speaker Senior Clinical Operations Lead, Biogen



Karen M. Winkfield, MD, PhD Guest Speaker Executive Director, Meharry-Vanderbilt Alliance





**LEANING IN: A WEBINAR SERIES** 

Practical Approaches to improving Diversity in Clinical Trials



## The Multi-Regional Clinical Trials Center (MRCT Center)

#### **Our Vision**

Improve the integrity, safety, and rigor of global clinical trials.

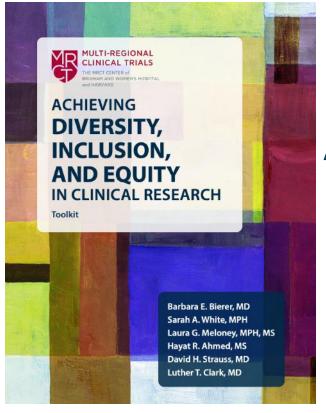
#### **Our Mission**

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









Achieving Diversity, Inclusion, Equity In Clinical Research

**Guidance and Toolkit** 

mrctcenter.org/diversity-in-clinical-trials

Released 6 August 2020



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# Leadership

- RADM Richardae Araojo, PharmD, MS, U.S. FDA
- Barbara E. Bierer, MD, MRCT Center
- Luther T. Clark, MD, Merck & Co., Inc.
- Milena Lolic, MD, U.S. FDA
- David H. Strauss, MD, Columbia University
- Sarah White, MPH, MRCT Center

#### MRCT Center staff:

- Carmen Aldinger, PhD, MPH
- Hayat Ahmed, MS
- Laura Meloney, MS, MPH
- Joshua Smith-Sreen, MPH

And the invaluable contributions of >50 workgroup members, representing:

- Patients, Patient Advocates
- Academia
- Pharmaceutical companies
- CROs
- Non-profit organizations
- Trade associations
- Government agencies
- Research institutes

Each serving in their individual capacity.



#### Guidance Document

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



mrctcenter.org/diversity-in-clinical-trials



# Focus on Clinical Research Workforce Development

#### Who comprises the Clinical Research Workforce?

- Clinicians
- Investigators
- Research team members
- Referring physicians
- Sponsors
- CROs
- Patient recruitment vendors
- ...anyone who is directly or indirectly involved in the research study

- Broadly inclusive
- Needs may differ



# Workforce development

- Sensitizing the clinical research workforce to issues of diverse participation
- Building the number of underrepresented minority investigators and study staff
- Provide cultural competence and implicit bias training of all staff
- Support diversity with health literacy and clear communication
- Involve physicians in community healthcare settings and ensure they understand clinical research



# Lack of Diverse Workforce impacts research

Original Paper | Published: 11 April 2016

Growing the Pipeline of Diverse HIV Investigators: The Impact of Mentored Research Experiences to **Engage Underrepresented Minority Students** 

Jonathan Fuchs 

M. Aminta Kouyate, Liz Kroboth & Willi McFarland

AIDS and Behavior 20, 249–257(2016) Cite this article

American Journal of Therapeutics 15, 3-11 (2008)

Racial Disparities Among Clinical Research **Investigators** 

Kenneth Getz, MBA\* and Laura Faden, BA



J Natl Med Assoc. 2005 Aug; 97(8): 1063-1077.

PMID: 16173321

Barriers to racial/ethnic minority application and competition for NIH research funding.

Vickie L. Shavers, Pebbles Fagan, Deirdre Lawrence, Worta McCaskill-Stevens, Paige McDonald, Doris Browne, Dan McLinden, Michaele Christian, and Edward Trimble

► Author information ► Copyright and License information Disclaimer

Published in final edited form as: Acad Med. 2013 April; 88(4): . doi:10.1097/ACM.0b013e31828589e3.

Mentoring Programs for Underrepresented Minority Faculty in Academic Medical Centers: A Systematic Review of the Literature

#### Health Promotion Practice



Increasing the Number of Underrepresented Minority Behavioral Health Researchers Partnering With Underresourced Communities: Lessons Learned From a Pilot Research Project Program

Theresa H. Cruz, PhD Matthew E. Borrego, PhD, Janet Page-Reeves, PhD

First Published February 26, 2020 Research Article https://doi.org/10.1177/1524839920907554

AIDS Research and Human Retroviruses, Vol. 34, No. 2 | Outcomes Research



## **Recruitment of Underrepresented Minority Researchers into HIV Prevention** Research: The HIV Prevention Trials **Network Scholars Program**

Sten H. Vermund M. Erica L. Hamilton, Sam B. Griffith, Larissa Jennings, Typhanye V. Dyer, Kenneth Mayer, and Darrell Wheeler

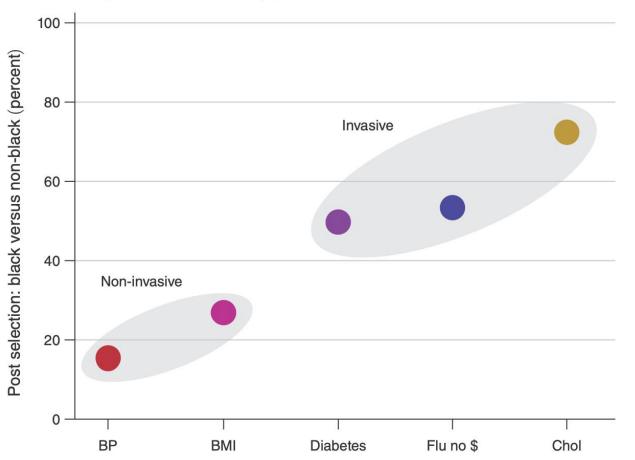
Published Online: 1 Feb 2018 https://doi.org/10.1089/aid.2017.0093



#### Does Diversity Matter for Health? Experimental Evidence from Oakland<sup>†</sup>

By Marcella Alsan, Owen Garrick, and Grant Graziani\*

Panel A. Post percent differences by preventives



- Concordance of race between doctor and patient improves compliance and health
- Effect increases with "invasiveness" of tests for preventive care

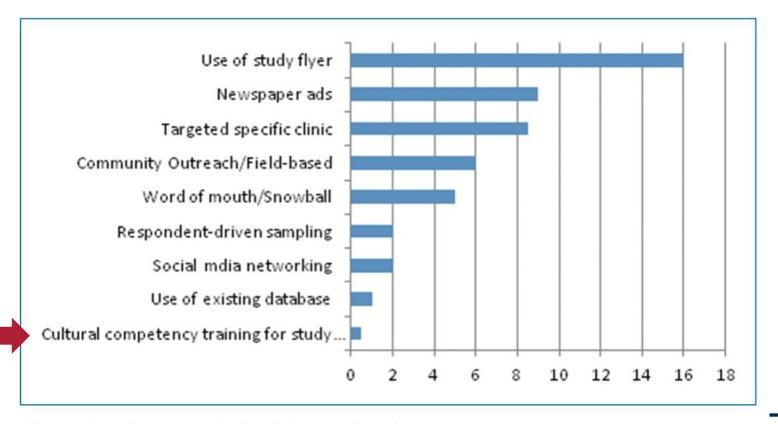
Alsan M, et al. American Economic Review. 2019 Dec;109(12):4071-111.



# Training of the workforce

# **Culturally Competent Strategies for Recruitment and Retention of African American Populations into Clinical Trials**

Jane Otado, Ph.D.<sup>1</sup>, John Kwagyan, Ph.D.<sup>1</sup>, Diana Edwards, Ph.D.<sup>1</sup>, Alice Ukaegbu, M.S.N., F.N.P.-B.C.<sup>1</sup>, Faun Rockcliffe, B.A.<sup>1</sup>, and Nana Osafo, M.S.<sup>1</sup>



答

Figure 1. Recruitment strategies data indicate number of response.

# Minimum expectations of workforce development

Commitment to recruiting and training a diverse clinical research workforce

Training research professionals, staff, and others in cultural and linguistic competency

Workforce Development

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Implicit bias training and respect of potential populations

Commitment to health literacy



# Public Commitment to Diversity in Clinical Research



The safety and efficacy of medical treatments are assessed primarily by clinical research; such research should reflect the population for whom the treatment is intended. [The organization] is committed to inclusion of diverse populations, including people of varying age, race, ethnicity, sex, gender, and other potential effect modifiers, to better reflect the population for whom the treatment is intended, in order to advance better health outcomes for all.

- Organizations should develop a model statement of commitment
- Statement can be aspirational (e.g., "...working towards inclusion") and modified as progress occurs

Ahmed HR, Strauss DH, Bierer BE. Committing to the Inclusion of Diverse Populations in Clinical Research. Therapeutic Innovation & Regulatory Science. 2020 Jan 2:1-3.



#### Cultural Considerations

- Cultures undergo change over time
- A workforce that creates and sustains a culturally informed and respectful environment will:
  - Understand the background and cultures included in the study population
  - Learn about diverse cultural heritages, norms, lifestyles
  - Develop preferred and respectful ways to communicate with intended populations
  - Be comfortable asking and listening as well as informing and talking
- Iterative process that is most effective if modeled by leaders in all stakeholder groups





# Cultural Example – Including Individuals of the Islamic Faith

Address in advance how to accommodate the enrollment of individuals of the Islamic faith:

- Times and places of prayer
- Participation during Ramadan
- Dress requirements and interactions between women and male clinician
- If a study visit requires Muslim participants to be at the clinic, ask how you can accommodate them.



# Training of Healthcare Providers

- Healthcare providers play a key role
  - Raise awareness of clinical research and specific clinical trials
  - Trusted resource to patients, explain research in context of patients' condition
  - Critical referral agent, essential collaborator, and participant supporter
- Healthcare providers face barriers
  - Limited time
  - Limited information about ongoing clinical trials
  - Limited knowledge regarding clinical trials, especially complex protocols
  - Fail to receive information about referred patients



# Training and Availability of Study Teams

 A well-trained study team / research staff can relieve clinical burden and enhance participant recruitment

# A few essential elements for comprehensive diversity training:

- ✓ Clinical research training
- ✓ Privacy and confidentiality training
- ✓ Trust and relationship building
- ✓ Implicit bias training
- ✓ Mindfulness tools for cultural considerations



# Recruiting and training a diverse clinical research workforce

Every stakeholder is responsible for increasing opportunities and improving mentorship and training of diverse investigators and study staff



- NIH Scientific Workforce Diversity Toolkit
- National Heart, Lung, and Blood Institute's (NHLBI)
   PRIDE Program
- Eli Lilly and Company in partnership with Center for Drug Development and Clinical Trials at Roswell Park Cancer Institute
- American Society of Clinical Oncology (ASCO)







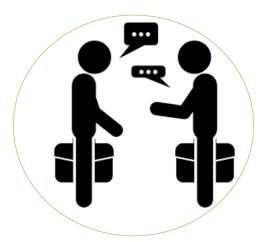




# Health Literacy and Clear Communication to Support Diversity

- Factors that influence an individual's health literacy:
  - Economic status
  - Education
  - Race
  - Ethnicity
  - Age
  - Disability
- The communicator is responsible for developing and sharing health information that is understandable to the listener
- Clear communication is important for successful engagement and inclusion of diverse populations







# Health literacy best practices

- Use of plain language
- Images relating to specific population
- Multi-format explanations of numeric information
- Application of clear design principles
- Translations and additional cultural considerations that contribute to the creation of materials that are designed specifically for a heterogeneous population.

For more information and examples, see the MRCT Center's Health Literacy in Clinical Research website at

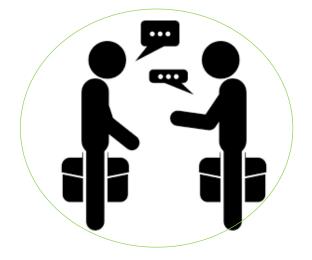
https://mrctcenter.org/health-literacy/

#### All information

- Education about research
- Informed consent documents
- Research procedures

#### Communications

- Written
- Oral





## The MRCT Center Launched a "Health Literacy in Clinical Research" Website

HEALTH LITERACY HOME | CONTACT



#### HEALTH LITERACY IN CLINICAL RESEARCH

START HERE | TRIAL LIFE CYCLE | BEST PRACTICES | RESOURCES BY ROLE

# WATCH OUR NEW CLINICAL RESEARCH VIDEO!

A helpful way to learn about clear communications and plain language in clinical research.



www.mrctcenter.org/health-literacy

#### **Tools and Resources**

Information on techniques that are key to successful research communications.



PLAIN LANGUAGE Resources



NUMERACY Resources



CLEAR DESIGN Resources



USABILITY TESTING Resources



CULTURAL CONSIDERATIONS Resources



INTERACTIVE TECHNIQUES Resources



GLOSSARY Resources



CONSENT GUIDE Resources



CASE STUDY LIBRARY Resources



EDUCATION & TRAINING Resources



RETURN OF RESULTS Resources



RESEARCH PARTICIPANTS' Resources

#### Recommendations for stakeholders

#### **RECOMMENDATIONS**

For Sponsors, Investigators, Providers, Clinical Research Sites and Healthcare Institutions:

- Develop a comprehensive workforce training and development program as part of the organization's strategic plan to recruit, train, and mentor a diverse workforce to achieve better intercultural responsiveness.
- Create and expand mentoring opportunities, including satellite or sister offices and connection networks, that are available for new investigators and study teams from underrepresented groups.
- Intentionally guide the clinical research team on the skills necessary to support, understand, and communicate with a diverse participant population through a comprehensive training plan that includes trust /relationship building, and training in implicit bias detection and reduction and in cultural competence and humility.
- Improve and encourage the career development and leadership opportunities available for people with diverse backgrounds.
- Establish a workforce that is able to adopt and implement health literacy best practices in clinical research to ensure an inclusive environment.

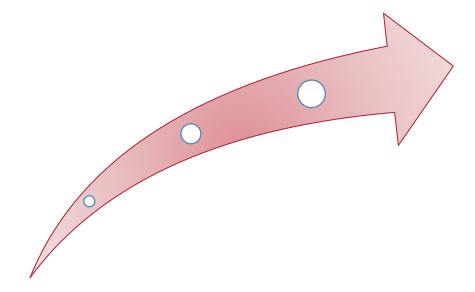


# Key Performance Indicators

# Workforce Development – Potential Key Performance Indicators (KPIs)

The importance of metrics

Progress takes time



Output indicators
Public statement endorsing workforce D&I principles available
D&I council established within organization
D&I council develops comprehensive workforce D&I strategy
Employee resource groups available at organization
Number of employees that received a comprehensive D&I training annually
Career development programs for underrepresented groups available at organization
Outcome indicators
High attendance of D&I programs across employee type
D&I principles cited in departmental SOPs

Increased proportion of leadership from underrepresented

Increased self-reported understanding of cultural humility, social identity and implicit bias on company-wide survey

D&I principles cited in commercial strategy



demographics

# Today's speakers



Racquel W. Bruton
Senior Clinical Operations

Senior Clinical Operations Lead Biogen

## Where Science meets Humanity...

- Listen, Learn, and Engage in diverse communities to move toward more inclusive research
- Increase in our current trial participation numbers
- Building sustained transparent trustworthy relationships with the community.
- Formed a Global Clinical Operations (GCO) UP Champions team
- These community outreach events drew over 1,700 attendees across the U.S. in 2019.
- Collaborations with the Center for Information and Study on Clinical Research Participation (CISCRP) & the National Minority Quality Forum (NMQF).



#### **Areas of Focus:**

"The success of any given workforce development program, however, is evident only through measuring improvement over time, which could be indicated by a shift in research study enrollment numbers, a value change in implicit association bias results, and/or through a statement of commitment from the executive level at an organization"

https://mrctcenter.org/diversity-in-clinical-trials/pg. 132

#### 2019:

- Community Engagement & Awareness
- Patient & HCP Insights
- Regulatory/Industry Working Groups
- Internal Awareness & Education

#### 2020:

- Community Engagement With Trusted Partners
- Study level plans
- Protocol Design
- Site Selection
- Departmental UP Champions

#### From Focus to **Action**

- Strategy Build-out:
  - Incorporate epidemiology data into US recruitment
  - Each study after 2020 will have an epidemiology goal prior to study startup
  - Align engagement goals with external vendors
    - CRO
    - 3<sup>rd</sup> party vendor
    - Community Advisory Board consisting of African Americans and Latinx members
    - Investigator meetings
  - Percentage analysis for all measured metrics



# Study Highlight-LUPUS

#### Background...

- For Lupus we know it predominantly affects women and disproportionately affects women of color who identify as Black, African American, Hispanic, Afro Hispanic, Latino/Latina and Indigenous American.
- Goal:
  - FEASIBILITY & SITE SELECTION
  - PATIENT INSIGHTS
    - Patient Advisory Board Insights
  - STUDY DESIGN
  - RECRUITMENT MATERIALS AND COMMUNITY ENGAGEMENT

- Lessons learned
  - Previous trial info
  - Patient journey and social listening
  - Findings are applicable to a diverse population.
  - Lupus UP Engagement Plan requires a robust <u>multifaceted</u> strategy including:
  - ACCESS: Improving access and opt-in rates of clinical trials
  - <u>EMPATHY</u>: Addressing the lack of trust
  - <u>ACTION</u>: Investigators and staff of color in communities of color
    - Strategy starts before the study activation.

# THANK YOU!



# Workforce Diversity & Improving Access to Clinical Trials

Karen Winkfield, MD, PhD

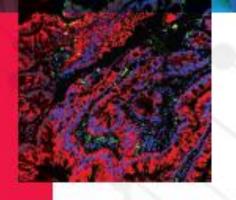
Health Equity Consultant
KW Health Equity Consulting, LLC
Executive Director, Meharry-Vanderbilt Alliance

Leaning in: A Webinar Series

Multi-Regional Clinical Trials Center

October 28, 2020







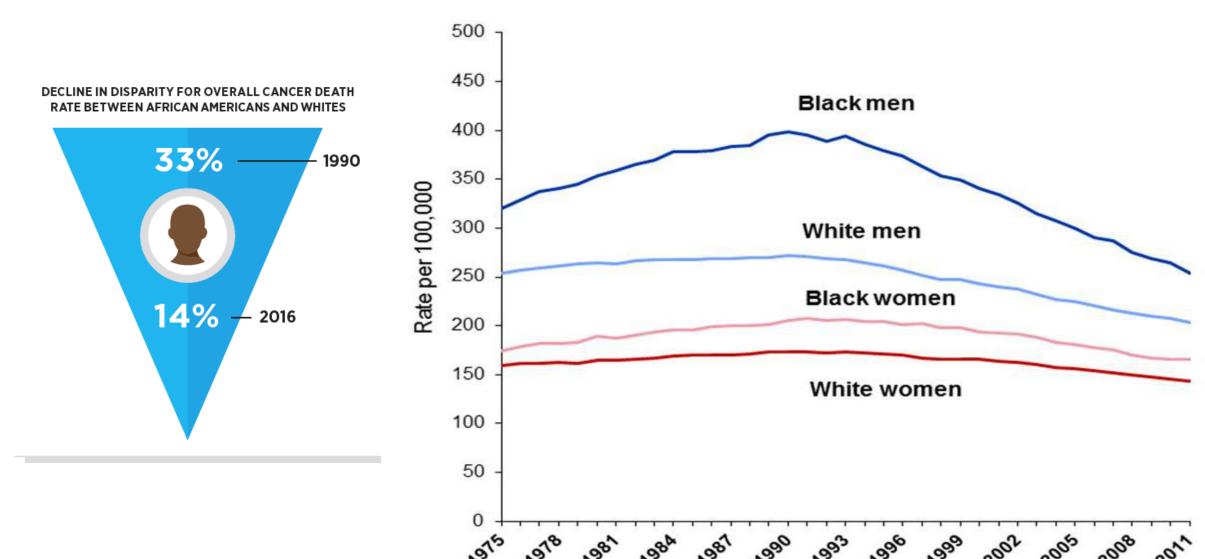
# AACR CANCER DISPARITIES PROGRESS REPORT 2020

Achieving the Bold Vision of Health Equity for Racial and Ethnic Minorities and Other Underserved Populations

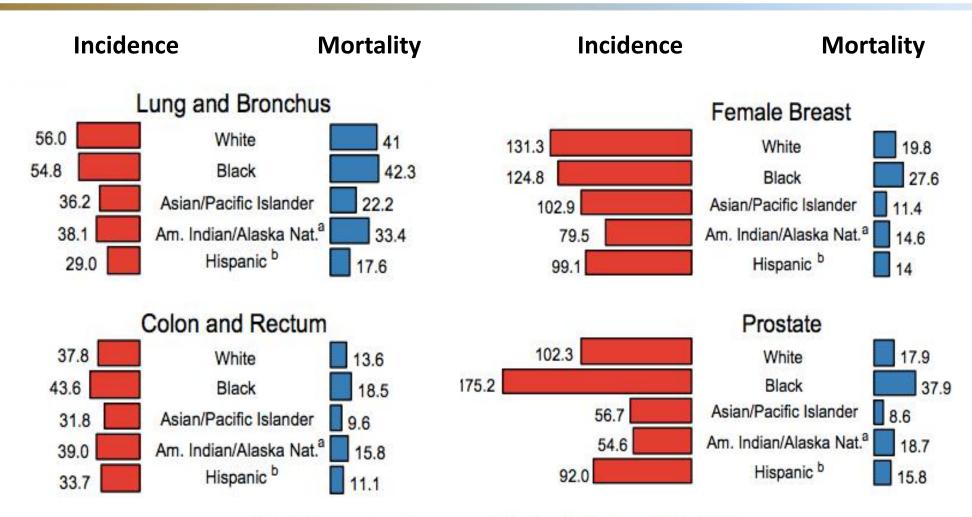
AACR.org CancerDisparitiesProgressReport.org #CancerDisparitiesReport



# Trends in Cancer Death Rates by Sex and Race, US, 1975-2011



# **Cancer Disparities**



SEER Cancer Incidence and US Death Rates, 2013-2017

By Cancer Site and Race/Ethnicity

# Health Disparities: Nature vs. Nurture

Biologic determinants

Social determinants

- Genetics
- Biology
- Comorbidities

- Socioeconomic status
- Access to care
- Sociocultural barriers



# CANCER

An Assessment of NIH Research and Programs for Ethnic Minorities and the Medically Underserved

\*\*\*\*\*\*\*\*\*

## The Charge for the IOM Committee (1998)

- 1. Review the status of cancer research relative to minorities and medically underserved populations within the NIH
- 2. Examining how well research results are communicated and applied to cancer prevention and treatment programs for minorities and medically underserved populations, and the adequacy of understanding of survivorship issues that uniquely affect minority and underserved communities
- 3. Examining the adequacy of NIH procedures for equitable recruitment and retention of minorities in clinical trials

## Report: What Should the NIH Do??

- Burden resources to SEER
- Research Office of Research on Minority Health
- Priority setting across NIH programs increase representation
- Clinical Trials report on recruitment/retention of minorities
- Survivorship plan to address the needs of minorities
- Monitoring increase NIH accountability to the U.S. Congress and public constituencies

## The Sullivan Commission (2004)

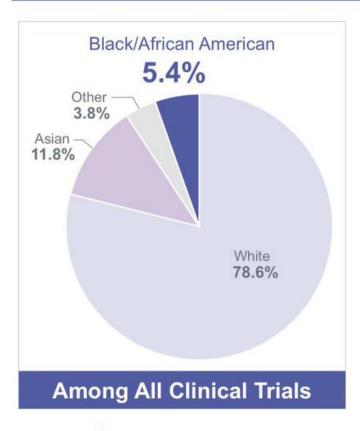
# MINORITIES IN THE HEALTH PROFESSIONS

A REPORT OF THE SULLIVAN COMMISSION ON DIVERSITY IN THE HEALTHCARE WORKFORCE

"...increasing ethnic diversity among physicians may be the most direct strategy to improve health care experiences for members of ethnic minority groups"

#### What About Clinical Trials??

#### Black/African American Clinical Trial Participation



Specific Therapeutic Areas (2015-16)

Black/African American 2.5%

**Cardiovascular Trials** 

Black/African American 2.74%

**Oncology Trials** 

- White participants represent about 78.6% of all clinical trial participants.
- Asian, Black/African American, and other groups represent 11.8%, 5.4%, and 3.8%, respectively.

When looking at specific therapeutic areas, Black/African Americans only represent 2.5% cardiovascular and 2.74% of oncology trial participants from 2015-2016 (FDA Global Trial Participation 2015-16) despite the prevalence of cardiovascular disease and aggressive cancers in this minority (Coakley, Fadiran et al. 2012).



## **Workforce Diversity:**

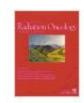
## Improving access to care

"Patients seeing physicians of their own race rate their physicians' decision-making styles as more participatory... Providing patients with access to a diverse group of physicians may lead to more patient involvement in care, higher levels of patient satisfaction, and better health outcomes."

Cooper-Patrick, et al. JAMA. 1999 Aug 11;282(6):583-9



#### International Journal of Radiation Oncology\*Biology\*Physics

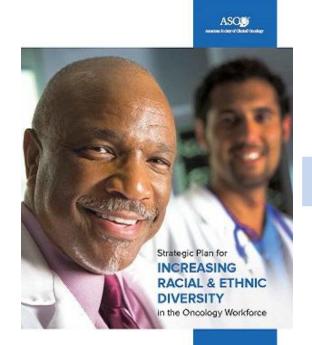


Volume 85, Issue 4, 15 March 2013, Pages 900-901

Editorial

#### Why Workforce Diversity in Oncology Matters

Karen M. Winkfield, MD, PhD\*. . Darlene Gabeau, MD, PhD†



## Diversity, Inclusion, and Representation: It Is Time to Act

Johnson B. Lightfoote, MD, MBA, FACR<sup>a</sup>, Curtiland Deville, MD<sup>b</sup>, Loralie D. Ma, MD, PhD<sup>c</sup>, Karen M. Winkfield, MD, PhD<sup>d</sup>, Katarzyna J. Macura, MD, PhD, FACR<sup>e</sup>

VOLUME 35 · NUMBER 22 · AUGUST 1, 2017

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

American Society of Clinical Oncology Strategic Plan for Increasing Racial and Ethnic Diversity in the Oncology Workforce

Karen M. Winkfield, Christopher R. Flowers, Jyoti D. Patel, Gladys Rodriguez, Patricia Robinson, Amit Agarwal, Lori Pierce, Otis W. Brawley, Edith P. Mitchell, Kimberly T. Head-Smith, Dana S. Wollins, and Daniel F. Hayes

## Diversity in Oncology Initiative

- Medical Student Rotation
- Resident Travel Award
- Diversity Mentoring Program
- Virtual Mentoring Program
- Oncology Scholars Rotation
- Bias Training for Scientific Reviewers





#### Advances in Radiation Oncology

Available online 7 July 2020

In Press, Corrected Proof (?)



Brief Opinion

### Why Racial Justice Matters in Radiation Oncology

Christina Hunter Chapman MD, MS a, b, Darlene Gabeau MD, PhD c, Chelsea C. Pinnix MD, PhD d, Curtiland Deville Jr. MD e, Iris C. Gibbs MD f, Karen M. Winkfield MD, PhD B △ ■

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https://doi.org/10.1016/j.adro.2020.06.013

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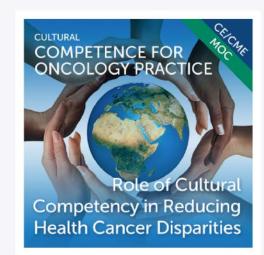
Self-Evaluation ▼

MOC Information ▼

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#### **FACULTY**



**Dr. Lovell A. Jones**MD Anderson

#### Role of Cultural Competency in Reducing Cancer Disparities

**Ollection: Cultural Competence for Oncology Practice** 

This course reviews basic definitions of culture, race, and ethnicity. Essential elements of cultural competence are described and practical strategies for achieving cultural competence are provided. The course includes discussion of bi-culturalism, cultural pluralism, cultural sensitivity and specificity, and linguistic competence.

**Credit Expires:** 9/30/2020 | **Max Credits:** 0.5 | **Available Certificates:** Continuing Pharmacy Education (CPE) Certificate, CME Certificate, Continuing Nursing Education (CNE) Certificate, Certificate of Completion, Certificate of Participation

#### **Learning Objectives:**

- Distinguish between the following terms that relate to culture: race vs. ethnicity, inequality vs. inequity, and health disparity vs. health care disparity.
- Describe essential elements for cultural competence.
- Discuss consequences that stem from of a lack of cultural awareness.
- Share strategies for creating a culturally competent health care environment.
- Examine examples that highlight cultural differences.

## **Assembling the Right Team**

- Social Workers
- Nurses/APPs
- Financial Counselors
- Navigators
- Community Health Workers
- Volunteers



**Engage the Community!!** 

Define

Align

Connect

Plan

#### **ELSEVIER**

#### Contemporary Clinical Trials Communications



Contemp Clin Trials Commun. 2020 Mar; 17: 100532.

Published online 2020 Jan 22. doi: 10.1016/j.conctc.2020.100532

PMCID: PMC7005557

PMID: 32055746

## Operational strategies in US cancer centers of excellence that support the successful accrual of racial and ethnic minorities in clinical trials

Jeanne M. Regnante, a, Nicole Richie, Lola Fashoyin-Aje, Laura Lee Hall, Quita Highsmith, J'Aimee Louis, Kenneth Turner, Spencer Hoover, Simon Craddock Lee, Evelyn González, Erin Williams, Homer Adams, III, Coleman Obasaju, Ify Sargeant, Jovonni Spinner, Christopher Reddick, Marianne Gandee, Madeline Geday, Julie Dang, Rayneisha Watson, and Moon S. Chen, Jr.

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Abstract Go to: 

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#### Background

Study populations in clinical research must reflect US changing demographics, especially with the rise of precision medicine. However, racial and ethnic minority groups (REMGs) have low rates of participation in cancer clinical trials.

## Thank you!!

www.drkarenwinkfield.com



@DrWinkfield

@3BlackDocs



## Study Design, Eligibility, Site Selection & Feasibility

November 18, 2020 11AM -12noon ET





Laura Meloney, MSc, MPH
Moderator
Program Manager,
MRCT Center





Theresa Devins, DrPH
Guest Speaker
Clinical Research
Professional





Practical Approaches to improving Diversity in Clinical Trials



Wednesdays 11AM -12noon ET



**LEANING IN: A WEBINAR SERIES** 

**Recording available** Community Awareness, Access, Knowledge

October 28, 2020 Workforce Development

**November 18, 2020** Study Design, Eligibility, Site Selection & Feasibility

**December 9, 2020** Study Conduct (Recruitment, Retention)

**January 13, 2021** Data Standards and Analysis

**January 27, 2021** Stakeholder Roles and Responsibilities

**February 10, 2021** Role of Data in Diversity: Genetics & Real World Data





#### Join us:



## MULTI-REGIONAL CLINICAL TRIALS

THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD



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