

# Practical Strategies for Diversity, Equity, and Inclusion in Clinical Lymphoma Research

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CLINICAL PROFESSOR OF MEDICINE,  
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# CONFLICTS OF INTEREST

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# Disparities in Cancer Care

## AACR CANCER DISPARITIES PROGRESS REPORT 2022

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

**AACR**  
American Association  
for Cancer Research®  
FINDING CURES TOGETHER™

AACR.org  
CancerDisparitiesProgressReport.org  
#CancerDisparitiesReport



Volume 18 / Issue 5 / May 2022

# JCO® Oncology Practice

An American Society of Clinical Oncology Journal

Disparities in Cancer Care and Scientific Knowledge in Hispanic/Latinx People in the United States  
*L.D. Bosserman et al*

ASCO AMERICAN SOCIETY OF CLINICAL ONCOLOGY

Wolters Kluwer

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## Cancer Disparities: A Chartbook



# ACCELERATING EQUITY: CANCER CARE FOR ALL

**AACI** Association of  
American  
Cancer Institutes

# LYMPHOMA SURVIVAL STATISTICS 2023

## Death rates, 2016-2020

Average annual rate per 100,000, age adjusted to the 2000 US standard population

Compared to

## Incidence rates, 2015-2019

Average annual rate per 100,000, age adjusted to the 2000 US standard population.

### Non-Hodgkin lymphoma

Incidence rate / Non-Hispanic white



Incidence rate / Hispanic



Incidence rate / American Indian and Alaska Native



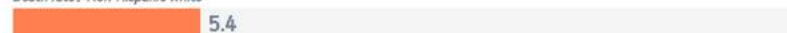
Incidence rate / Non-Hispanic black



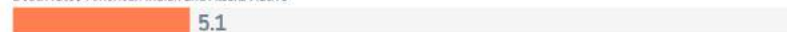
Incidence rate / Asian and Pacific Islander



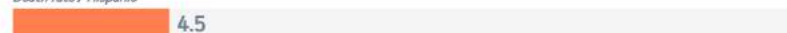
Death rate / Non-Hispanic white



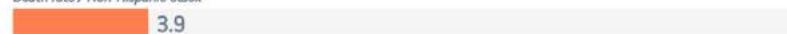
Death rate / American Indian and Alaska Native



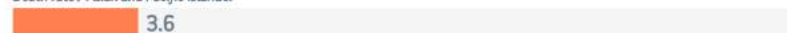
Death rate / Hispanic



Death rate / Non-Hispanic black



Death rate / Asian and Pacific Islander



Data Source: National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention, 2022

Data Source: North American Association of Central Cancer Registries (NAACCR), 2022

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CancerStatisticsCenter.cancer.org

## Death rates, 2016-2020

Average annual rate per 100,000, age adjusted to the 2000 US standard population

Compared to

## Incidence rates, 2015-2019

Average annual rate per 100,000, age adjusted to the 2000 US standard population.

### Hodgkin lymphoma

Incidence rate / Non-Hispanic white



Incidence rate / Non-Hispanic black



Incidence rate / Hispanic



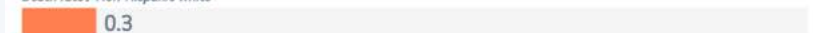
Incidence rate / American Indian and Alaska Native



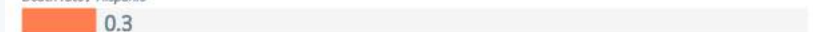
Incidence rate / Asian and Pacific Islander



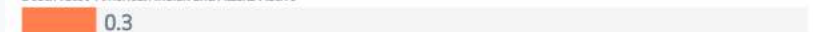
Death rate / Non-Hispanic white



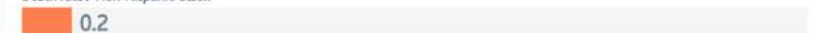
Death rate / Hispanic



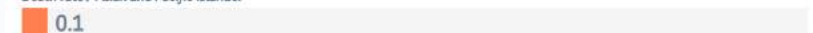
Death rate / American Indian and Alaska Native



Death rate / Non-Hispanic black



Death rate / Asian and Pacific Islander



Data Source: National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention, 2022

Data Source: North American Association of Central Cancer Registries (NAACCR), 2022

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# DISPARITIES IN LYMPHOMA OUTCOMES AND RESEARCH

## Previous Studies Highlighting Disparities for Black DLBCL Patients

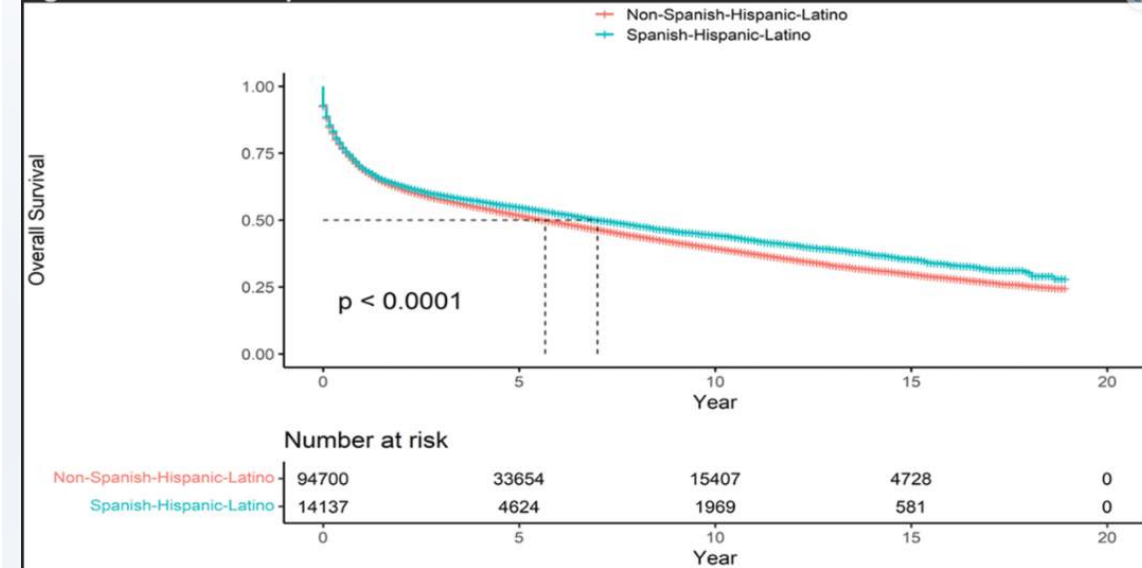
Study	Years Evaluated	Number of pts (N)	Study Conclusions (Black Patients)
Blansky et al. (2021) <sup>1</sup> <b>Single Institution</b>	2005-2016	White: 136 Black: 106	<u>Similar</u> OS ↓ age, = stages
Shenoy et al. (2009) <sup>2</sup> <b>Single Institution</b>	1981-2009	White: 348 Black: 107	<u>Similar</u> OS ↓ age, ↑ stage
The et al. (2007) <sup>1</sup> <b>Single Institution</b>	1995-2007	White: 277 Black: 32	<u>Shorter</u> OS ↓ age, ↑ stage
Flowers et al. (2013) <sup>4</sup> <b>Two Institution</b>	1981-2010	White: 701 Black: 144	<u>Shorter</u> OS ↓ age, ↑ stage
Ayers et al. (2019) <sup>5</sup> <b>SEER database</b>	2001-2015	White: 5,951 Black: 1,592	<u>Shorter</u> OS ↓ age, ↑ stage
Shenoy et al. (2011) <sup>6</sup> <b>SEER database</b>	1992-2007	White: 32,121 Black: 2,512	<u>Shorter</u> OS ↓ age, ↑ stage

<sup>1</sup>The A. et al. [ASH abstract] Blood 2007. <sup>2</sup>Shenoy PJ, et al. [ASH abstract] Blood 2009. <sup>3</sup>Flowers CR, et al. *Leukemia Lymphoma* 2013. <sup>4</sup>Blansky D, et al. *Leukemia Lymphoma*. 2021. <sup>5</sup>Shenoy PJ, et al. *Cancer*. 2011. <sup>6</sup>Ayers AA, et al. *Clin Lymphoma Myeloma Leuk*. 2019.

Ermann et al, ASCO, 2022, JCO, 2022 40:16\_suppl, 7507-7507

## Racial Disparities in DLBCL in Hispanics: SEER data

Figure 1. Survival Analysis for DLBCL.



Rosas et al. Racial and Ethnic Disparities for Diffuse Large B-Cell Lymphoma: A Surveillance, Epidemiology, and End Results (SEER) Database Analysis with Emphasis on Hispanics. *Blood* 2022; 140 (Supplement 1): 6695–6696. doi: <https://doi.org/10.1182/blood-2022-159201>

Are there Outcomes Disparities in Clinical Lymphoma Outcomes in the US?

# Racial Disparities Affecting Black Patients With Diffuse Large B-cell Lymphoma.

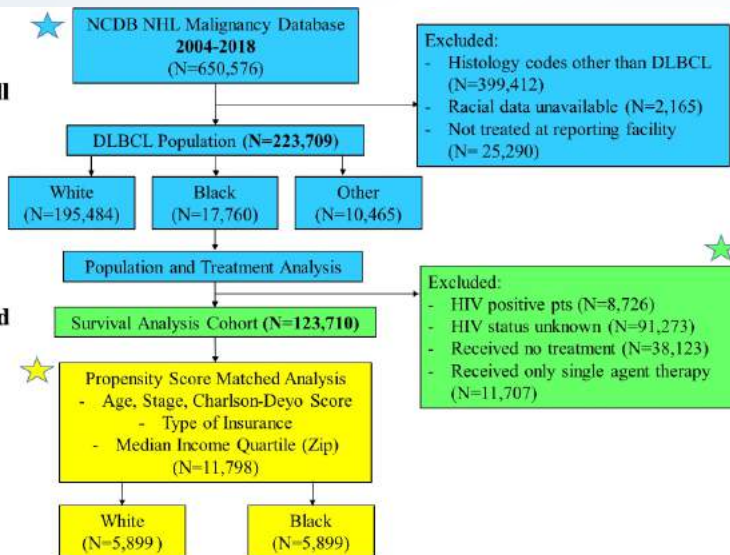
## Methods

### Diffuse Large B-cell Lymphoma

### Survival Analysis

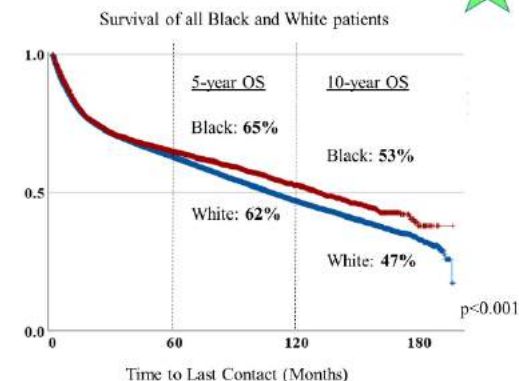
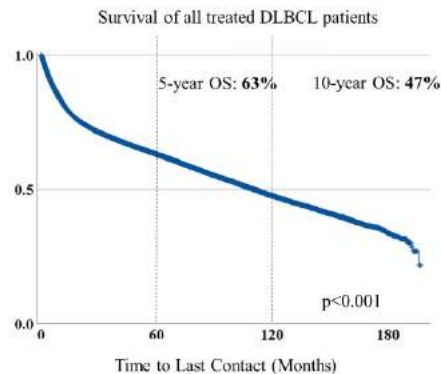
- Kaplan Meier
- Cox Regression

### Propensity Matched Analysis



## Results: Overall Survival of All Pts and OS of Black and White Pts

At a median follow-up of 3.7 years median OS for HIV-negative DLBCL patients treated with multiagent chemotherapy was 9 years (95% CI, 8.9-9.2 years)



## Limitations of this Study

- Retrospective nature, relies on facility reported data
- No granularity on prognostic information (COO, bulk, DHL)
- No data on # of cycles, chemotherapy given, doses received
- Lack of imaging data (i.e. CT scans or PET CT)



## Summary and Conclusions

We report the largest retrospective study (223,709 patients) evaluating racial disparities and survival outcomes amongst Black patients with Diffuse Large B-cell Lymphoma

Disparities Affecting Black patients with DLBCL	
Demographic and Disease Specific	Survival Outcomes
<ul style="list-style-type: none"> <li>&gt; Younger at diagnosis                             <ul style="list-style-type: none"> <li>• Adverse insurance status</li> <li>• Median income disparity (Zip)</li> </ul> </li> <li>&gt; HIV positivity</li> <li>&gt; More likely to have Stage IV disease</li> <li>&gt; B-symptoms</li> <li>&gt; Higher rate of Medical Co-Morbidities</li> <li>&gt; Less likely to receive Radiation Therapy</li> </ul>	<ul style="list-style-type: none"> <li>OS was most likely affected by younger age at diagnosis for Black patients.</li> <li>&gt; Shorter OS for age:                             <ul style="list-style-type: none"> <li>• ≤ 60 and 61-79</li> </ul> </li> <li>&gt; Similar OS for age:                             <ul style="list-style-type: none"> <li>• ≥ 80</li> </ul> </li> <li>&gt; Independently associated with increased risk of death (HR 1.06)</li> </ul>

- Propensity Matched Analysis:
- > OS showed no significant difference when controlling for surrogate markers of health care access
  - > Suggesting healthcare access contributes to observed disparities

- Future Directions:
- > **Further work is warranted to close these care gaps**
  - > Future studies should attempt interventions to bridge healthcare access disparities among underrepresented and minority patients

# Causes of Racial Disparities in Cancer Occurrence and Outcomes

- Longstanding inequalities in wealth resulting in differences in risk factor exposures and access to equitable cancer prevention, early detection, and treatment
- Disproportionate wealth stems from hundreds of years of structural racism, including segregationist and discriminatory policies in criminal justice, housing, education, and employment, altered balance of prosperity, security, and other social determinants of health
- The social determinants of health are defined by the WHO as the conditions in which individuals are born, grow, live, work, and age
- Structural racism refers to the totality of ways in which societies foster racial discrimination through mutually reinforcing systems of housing, education, employment, earnings, benefits, credit, media, health care, and criminal justice

1. Siegel, RL, Miller, KD, Wagle, NS, Jemal, A. Cancer statistics, 2023. *CA Cancer J Clin.* 2023; 73( 1): 17- 48. doi:[10.3322/caac.21763](https://doi.org/10.3322/caac.21763)

2. Ward E, Jemal A, Cokkinides V, et al. Cancer disparities by race/ethnicity and socioeconomic status. *CA Cancer J Clin.* 2004;**54**(2):78-93. doi:[10.3322/canjclin.54.2.78](https://doi.org/10.3322/canjclin.54.2.78)

3. Bach PB, Schrag D, Brawley OW, Galaznik A, Yakren S, Begg CB. Survival of Blacks and Whites after a cancer diagnosis. *JAMA.* 2002;**287**(16):2106-2113. doi:[10.1001/jama.287.16.2106](https://doi.org/10.1001/jama.287.16.2106)

4. Bailey ZD, Krieger N, Agenor M, Graves J, Linos N, Bassett MT. Structural racism and health inequities in the USA: evidence and interventions. *Lancet.* 2017;**389**(10077):1453-1463. doi:[10.1016/S0140-6736\(17\)30569-x](https://doi.org/10.1016/S0140-6736(17)30569-x)

# DATA APPLICABILITY TO RACIALLY DIVERSE POPULATIONS

- Clinical trials clinician interactions and disease assessments may result in higher quality care
- Non inclusion of underrepresented groups in trials generates inapplicable clinical data to these patients, both for efficacy and safety. **DIVERSITY = SAFETY**
- Access to clinical trials is a moral imperative, as the treatments being tested are at the forefront of clinical innovation and should be equally accessible
- Trial underrepresentation in a world of big data engenders further:
  - ✓ **Data absenteeism** (ie, lack of data representation from underprivileged groups)
  - ✓ **Data chauvinism** (ie, faith in the size of data without considerations for quality and contexts)
  - ✓ **DATA HALLUCINATION** (ie, the assumption and use of non-existent data to generalize treatment recommendations, outcomes and results)

1. Peppercorn JM, Weeks JC, Cook EF, Joffe S. Comparison of outcomes in cancer patients treated within and outside clinical trials: conceptual framework and structured review. Lancet. 2004;363(9405):263-270.
2. Nipp RD, Hong K, Paskett ED. Overcoming barriers to clinical trial enrollment. Am Soc Clin Oncol Educ Book. 2019;39(39):105-114.
3. Unger JM, Cook E, Tai E, Bleyer A. The role of clinical trial participation in cancer research: barriers, evidence, and strategies. Am Soc Clin Oncol Educ Book. 2016;35(36):185-198.
4. Lee EWJ, Viswanath K. Big data in context: addressing the twin perils of data absenteeism and chauvinism in the context of health disparities research. J Med Internet Res. 2020;22(1):e16377.
5. O'Donnell PH, Dolan ME. Cancer pharmacoethnicity: ethnic differences in susceptibility to the effects of chemotherapy. Clin Cancer Res. 2009;15(15):4806-4814.
6. Hantel A, Luskin MR, Garcia JS, Stock W, DeAngelo DJ, Abel GA. Racial and ethnic enrollment disparities and demographic reporting requirements in acute leukemia clinical trials. Blood Adv. 2021 Nov 9;5(21):4352-4360. doi: 10.1182/bloodadvances.2021005148. PMID: 34473244; PMCID: PMC8579250.



# DATA APPLICABILITY TO RACIALLY DIVERSE POPULATIONS

## RESEARCH SUMMARY

### Polatuzumab Vedotin in Previously Untreated Diffuse Large B-Cell Lymphoma

Tilly H et al. DOI: 10.1056/NEJMoa2115104

#### CLINICAL PROBLEM

Patients with diffuse large B-cell lymphoma (DLBCL) are typically treated with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone (R-CHOP), but up to 40% will have refractory disease or relapse after an initial response. Use of polatuzumab vedotin — an antibody–drug conjugate targeting CD79b, which is expressed on the surface of malignant B cells — could improve outcomes in DLBCL.

#### CLINICAL TRIAL

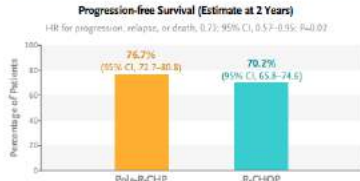
**Design:** An international phase 3, double-blind, randomized, placebo-controlled trial compared a modified R-CHOP regimen (pola-R-CHP), in which polatuzumab vedotin replaced vincristine, with standard R-CHOP in patients with previously untreated intermediate-risk or high-risk DLBCL.

**Intervention:** 879 patients were assigned to six 21-day cycles of pola-R-CHP or R-CHOP, followed by two cycles of rituximab monotherapy. The primary end point was investigator-assessed progression-free survival.

#### RESULTS

**Efficacy:** After a median follow-up of 28.2 months, the percentage of patients surviving without progression was significantly higher in the pola-R-CHP group than in the R-CHOP group.

**Safety:** The types and incidences of any adverse events, as well as grade 3 or 4 adverse events, were generally similar in the two groups. No new safety signals emerged.



## THE NEW ENGLAND JOURNAL OF MEDICINE

## RESEARCH SUMMARY

### Axicabtagene Ciloleucel as Second-Line Therapy for Large B-Cell Lymphoma

Locke FL et al. DOI: 10.1056/NEJMoa2116133

#### CLINICAL PROBLEM

For patients with relapsed or refractory large B-cell lymphoma after first-line chemoimmunotherapy, standard second-line treatment includes salvage chemoimmunotherapy and, for patients with a response, high-dose chemotherapy with autologous stem-cell transplantation, but the prognosis for many is poor. The autologous anti-CD19 chimeric antigen receptor (CAR) T-cell therapy axicabtagene ciloleucel (axi-cel) is a potential second-line treatment in such patients.

#### CLINICAL TRIAL

**Design:** An international, randomized, phase 3 trial compared axi-cel with standard care as second-line treatment in patients with early refractory or relapsed large B-cell lymphoma.

**Intervention:** 359 adults with refractory or relapsed disease no more than 12 months after the completion of first-line chemoimmunotherapy were randomly assigned to receive axi-cel or standard care (platinum-based chemoimmunotherapy, followed by high-dose chemotherapy and autologous stem-cell transplantation in those with a response). The primary end point was event-free survival.

#### RESULTS

**Efficacy:** At a median follow-up of 24.9 months, the median event-free survival was significantly longer in the axi-cel group than in the standard-care group.

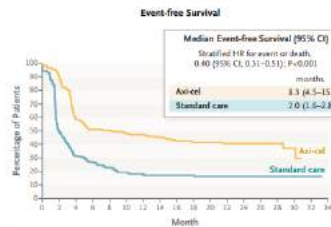


Table 1. Demographic and Clinical Characteristics of the Patients at Baseline.\*

Characteristic	Axi-cel (N=180)	Standard Care (N=179)	Total (N=359)
Race or ethnic group — no. (%)†			
American Indian or Alaska Native	0	1 (1)	1 (<1)
Asian	12 (7)	10 (6)	22 (6)
Black	11 (6)	7 (4)	18 (5)
Native Hawaiian or other Pacific Islander	2 (1)	1 (1)	3 (1)
White	145 (81)	152 (85)	297 (83)
Other	10 (6)	8 (4)	18 (5)

## Regular Article

### CLINICAL TRIALS AND OBSERVATIONS

### International prognostic indices in diffuse large B-cell lymphoma: a comparison of IPI, R-IPI, and NCCN-IPI

Amy S. Ruppert,<sup>1</sup> Jesse G. Dixon,<sup>2</sup> Gilen Salles,<sup>3</sup> Arna Wall,<sup>4</sup> David Cunningham,<sup>5</sup> Viola Paschelke,<sup>6</sup> Corinne Haican,<sup>7</sup> Hervé Tilly,<sup>8</sup> Hervé Ghesquieres,<sup>9</sup> Maria Zapater,<sup>10</sup> Jocelyne Flament,<sup>11</sup> Christopher Flowers,<sup>12</sup> Dian Shi,<sup>13</sup> and Norbert Strausz<sup>14</sup>

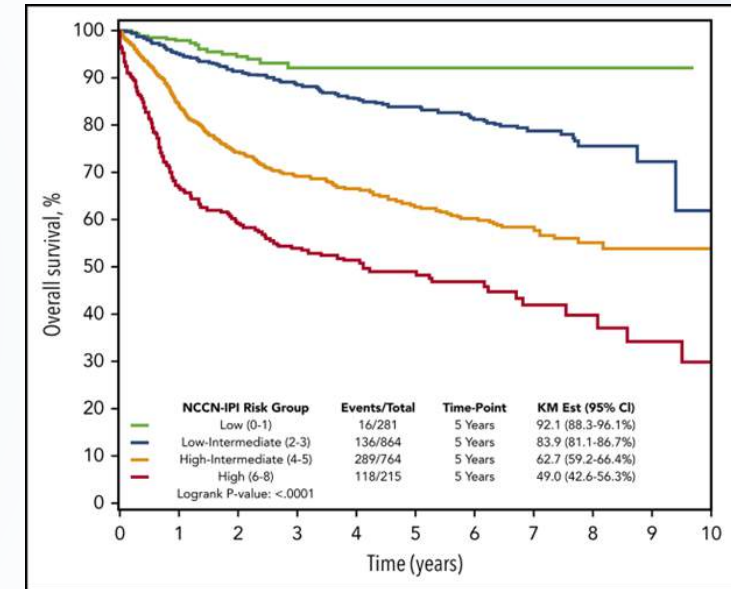


Table 1. Baseline patient characteristics (N = 2124)

Characteristic	Data
Age, median (range), y	63 (18–83)
Age, y	
≤40	276 (13)
41–60	650 (31)
61–75	1026 (48)
>75	172 (8)
Males	1198 (56)

No Racial Data Known or Reported

Table 1. Demographic and Clinical Characteristics at Baseline (Intention-to-Treat Population).\*

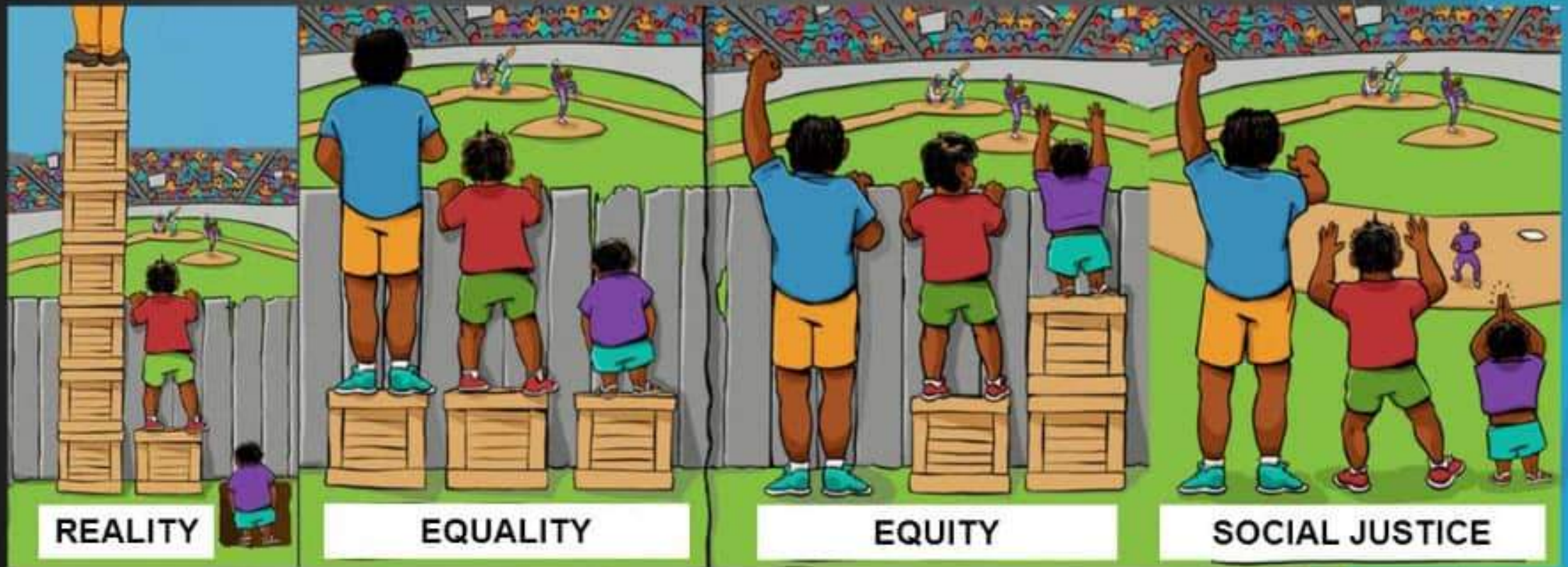
Characteristic	Pola-R-CHP (N=440)	R-CHOP (N=439)
Geographic region — no. (%)†		
Western Europe, United States, Canada, and Australia	302 (68.6)	301 (68.6)
Asia	81 (18.4)	79 (18.0)
Rest of world	57 (13.0)	59 (13.4)

Data Absenteeism

Data Chauvinism

Data Hallucination

# Equality vs. Equity vs. Social Justice



“



*"Our lives begin to  
end the day we  
become silent about  
things that matter."*

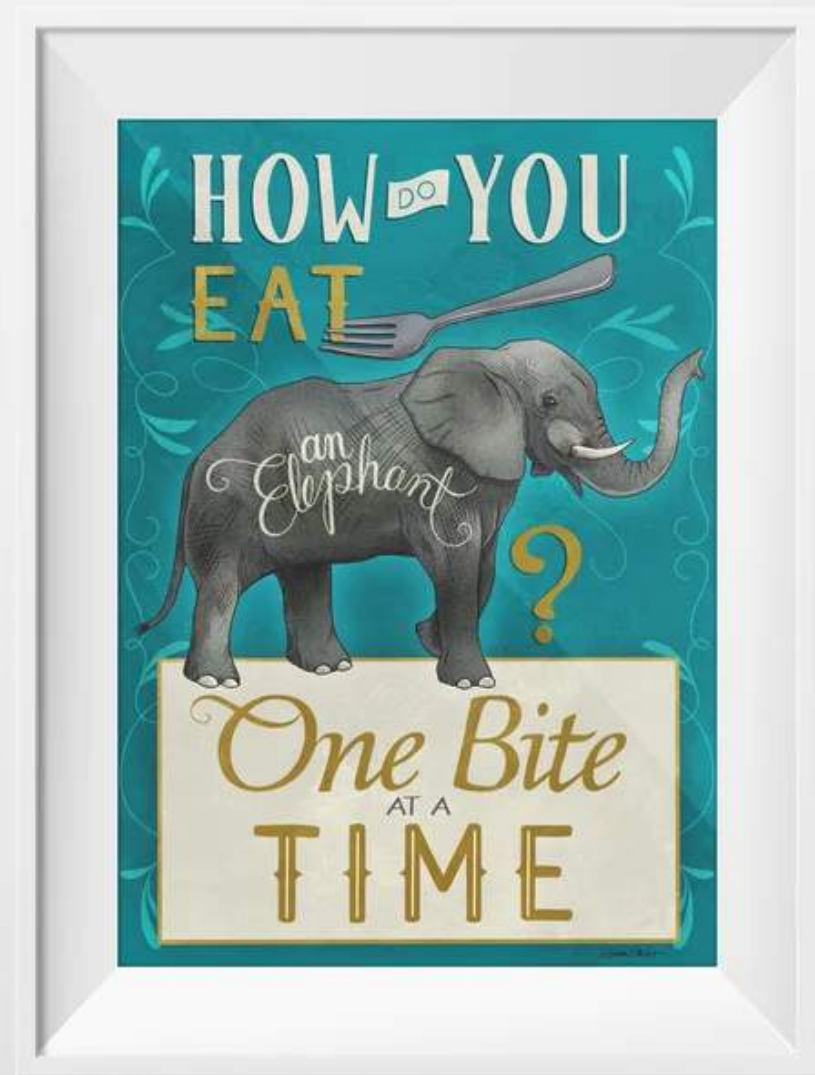
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Dr. Martin Luther King, Jr  
March 8, 1965, Selma, Alabama

**CLINICAL CANCER**  
**RESEARCH**  
**DISPARITIES IN**  
**LYMPHOMA:**  
**WHAT CAN “WE” DO?**

**How to eat an elephant**  
**101**

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# CONQUERING LYMPHOMA RESEARCH DISPARITIES

**fe·do·ra / fə'dôrə /**  
n. a low, soft felt hat with a curled brim and the crown creased lengthwise



<https://en.wikipedia.org/wiki/Fedora>

## **FDORA** Food and Drug Omnibus Reform Act of 2022

H.R. 2617

One Hundred Seventeenth Congress  
of the  
United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Monday,  
the third day of January, two thousand and twenty-two

### An Act

Making consolidated appropriations for the fiscal year ending September 30, 2023,  
and for providing emergency assistance for the situation in Ukraine, and for  
other purposes.

Be it enacted by the Senate and House of Representatives of  
the United States of America in Congress assembled,

#### SECTION 1. SHORT TITLE.

This Act may be cited as the "Consolidated Appropriations  
Act, 2023".

### CHAPTER 1—CLINICAL TRIAL DIVERSITY AND MODERNIZATION

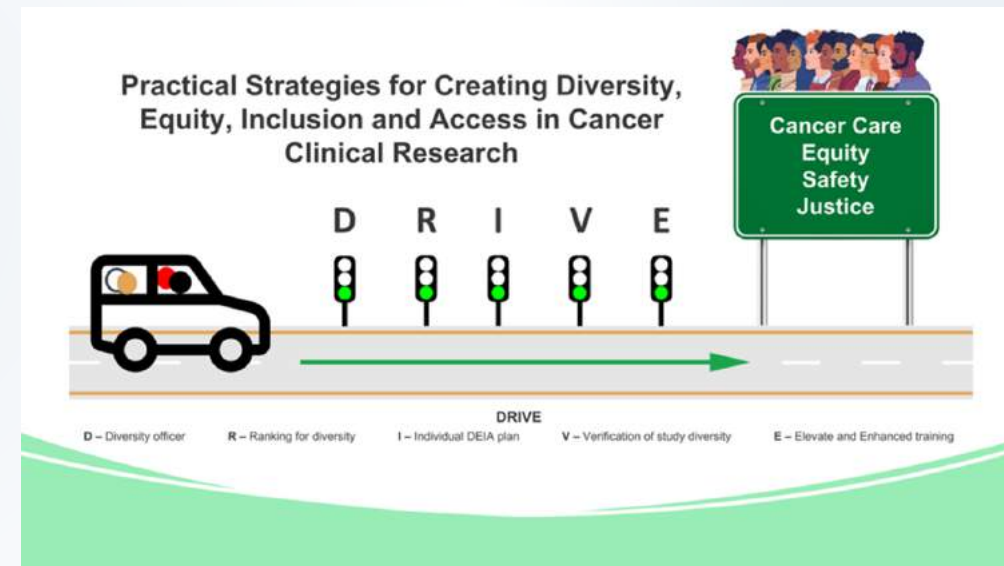
#### SEC. 3601. DIVERSITY ACTION PLANS FOR CLINICAL STUDIES.

(a) DRUGS.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(z)(1) With respect to a clinical investigation of a new drug that is a phase 3 study, as defined in section 312.21(c) of title 21, Code of Federal Regulations (or successor regulations), or, as appropriate, another pivotal study of a new drug (other than bio-availability or bioequivalence studies), the sponsor of such drug shall submit to the Secretary a diversity action plan.

## **DRIVE**

Practical strategies for creating diversity,  
equity, inclusion, and access in cancer  
clinical research



# The MYTH: Black Patient's Refuse to Participate in Clinical Trials

Representativeness of Black Patients in in NCI sponsored and Pharma-sponsored trials

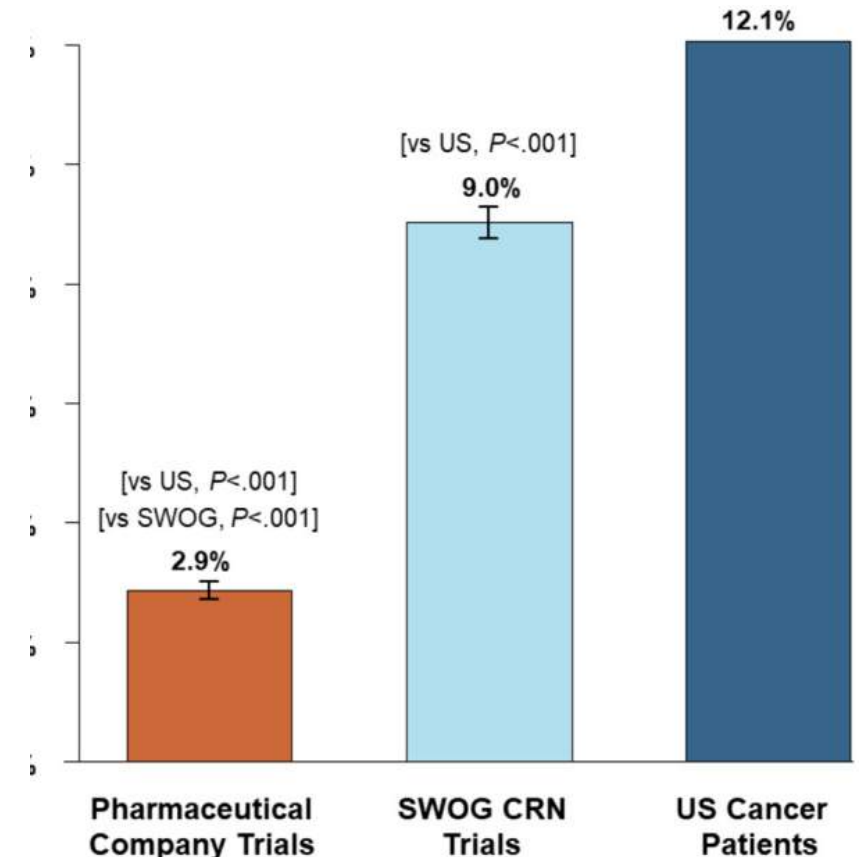
5 cancer types in between 2008-2018

358 trials: N=93,825

Pharmaceutical company-sponsored trials: 85; N=46,313

SWOG Cancer Research Network trials: N=47,512

Blacks in pharmaceutical company-sponsored trials compared with SWOG trials 2.9% vs 9.0%

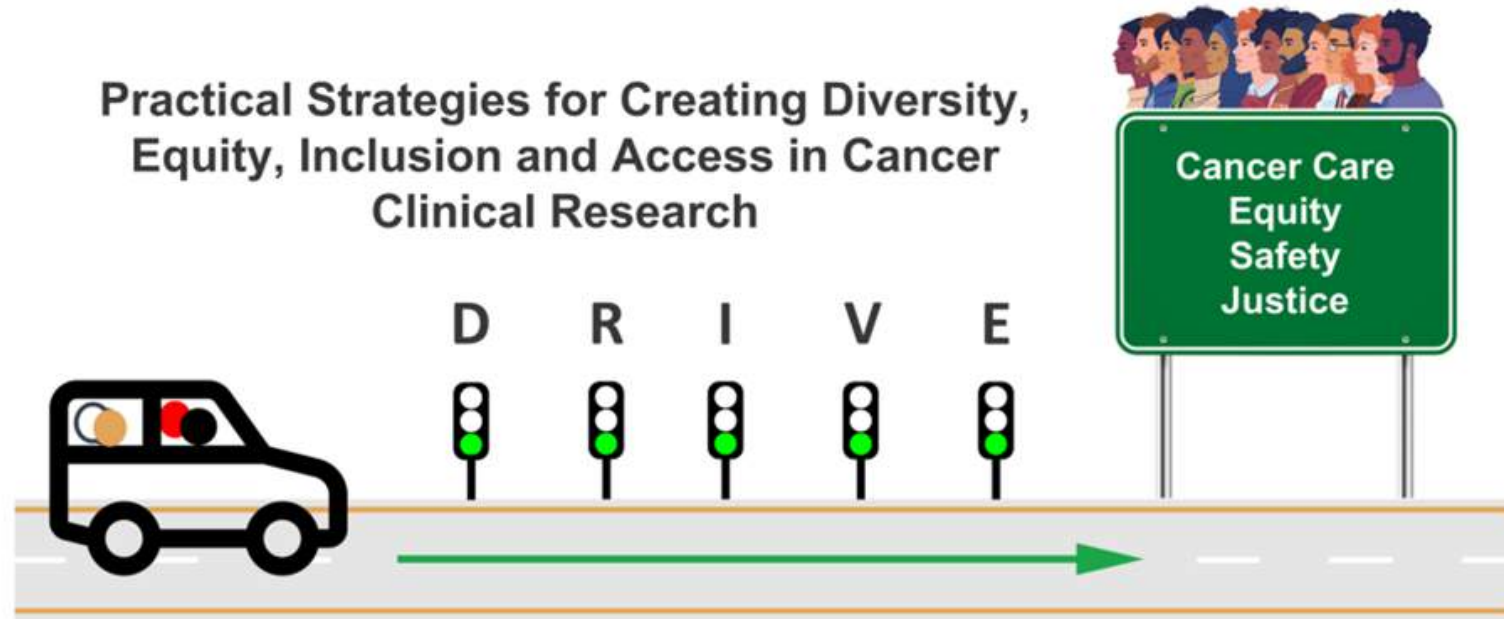


# Food and Drug Omnibus Reform Act of 2022 (“FDORA”)

- Legislation Requiring Guidance on Clinical Research Diversity and Modernization
- Sponsors are required to submit to FDA “diversity action plans” for Phase III and Pivotal trials for drugs and devices, unless otherwise waived or excepted
- FDA is tasked with updating guidance on diversity action plans for clinical studies and hosting public stakeholder workshops focused on enhancing clinical study diversity.
- Within one year, the FDA is to, as applicable, issue or revise guidance on the appropriate use of decentralized clinical studies:
  1. Recommendations for incorporation of data collection methodologies using digital health technologies in clinical trials to collect data remotely;
  2. Considerations for privacy and security protection for clinical trial data, including compliance with “HIPAA” and the Common Rule;
  3. Recommendations regarding data and information needed to demonstrate that a digital health technology is fit-for-purpose for a clinical trial;
  4. Recommendations for increasing access to, and the use of, digital health technologies in clinical trials to facilitate inclusion of diverse and underrepresented populations;
  5. Recommendations on the use of clinical trial designs that involve concurrent conduct of different or multiple clinical trial phases;
  6. Recommendations for how to streamline trial logistics to facilities for efficient collection and analysis of data, including through interim analyses; and
  7. Recommendations for communications between sponsors and the FDA on the development of seamless, concurrent, or other adaptive clinical trial designs.

# DRIVE

## Practical Strategies for Creating Diversity, Equity, Inclusion and Access in Cancer Clinical Research



### DRIVE

D – Diversity officer

R – Ranking for diversity

I – Individual DEIA plan

V – Verification of study diversity

E – Elevate and Enhanced training

Practical strategies for creating diversity, equity, inclusion, and access in cancer clinical research: DRIVE.

Birhiray MN, Birhiray RE. Blood Adv. 2022 Aug 25: Online ahead of print.



# Diversity Officer

- NIH commissioned GREENBERG REPORT, 1967: Established DSMBs to oversee and ensure safety and the validity of an ongoing clinical trials
- “The problem to be studied is an important one that must be resolved (a) from a purely scientific point of view, and or (b) for the benefit of mankind through improved methods of prevention, diagnosis and or therapy”

## **SAFETY = DIVERSITY**

- Major corporations: Chief Diversity Officer; Strategist to promote DEIA
- All clinical trials must include a **Diversity Officer** who is tasked just like a **DSMB** in safety to ensure a diversity plan is established, maintained, and modifiable during the study to meet accrual goals of inclusion and diversity

# Diversity Officer: RESPONSIBILITIES

- Prospectively develop an achievable, flexible, and monitorable DEIA Plan trials in accordance with FDA guidance on clinical trial diversity.
- Establish an infrastructure to monitor and adjust recruitment efforts prospectively.
- Identify impediments to meeting accrual goals at the micro- and macro-levels with proposed solutions
- Develop language and culturally appropriate study materials to promote minority accrual.
- Identify potential scientific questions and study design solutions based on trial barriers, modifications, and results, and improve methods of research in keeping with the Greenberg report's report .
- Advise study sponsor(s), principal investigators, steering committees, and DSMB on potential challenges and solutions.
- Liaise and communicate with other Diversity Officers (e.g., institutional diversity officers) to improve and remove barriers to diverse study enrollment and promote steps for the achievement of DEIA goals.

# Diversity Officer: QUALIFICATIONS

- a. Training in cancer research. Examples include persons with MD, PhD, AP/NP, PharmD degrees.
- b. Training in cultural awareness, humility, sensitivity, appropriateness, and diversity.
- c. An understanding of historical factors precluding potential enrollment in clinical trials. including, but not limited to, the Tuskegee syphilis study, Nuremberg code,
- d. Training in leadership, negotiation, and communications skills.
- e. Training and understanding of current recommendations and guidance on strategies to promote clinical trial diversity.
- f. To avoid conflicts of interest, diversity officers must be independent of study principal investigators.

# Diversity Officer: TRAINING

- a. Clinical study design and statistics.
- b. Historical issues relating to diversity: slavery, racism, sexism, gender, and sexuality.. This includes but is not limited to: the Tuskegee syphilis study, the Walter Reed Yellow Fever experiments, the Terre Haute experiments, and the background and development of the Nuremberg Code.
- c. Medical ethics and regulatory law and practice relating to clinical research.
- d. Cultural sensitivity, humility, and awareness training.
- e. The interplay between safety and diversity and an understanding of the Greenberg report and Declaration of Helsinki.
- f. The economic impact and implications of clinical research diversity, the economic promoters and inhibitors of research participation in diverse communities.
- g. Social construction (based on the notion that human definition and interpretation is shaped by cultural and historical contexts) including cultural factors and drivers in diverse communities.
- h. The regulatory requirements that impact clinical trial diversity.
- i. Leadership and negotiation related to clinical trial development and conduct.
- j. Additional elements of the training of diversity officers should include the recommendations of the AAMC Report on The Role of the Chief Diversity Officer in Academic Health Centers

# R: RANKING: “Informational tool”

DRIVE RANK SCORE	Study racial or nationality enrollment of the sum of all minority groups relative to the epidemiology of the disease§.
0	≤20% of the sum of all minority groups relative to the epidemiology of the disease.
1	21-40% the sum total of all minority groups relative to the epidemiology of the disease and at least one minority groups* not reaching 50% relative to the epidemiology of the disease.
2	21-40% the sum of all minority groups relative to the epidemiology of the disease and at least one minority group* reaching 50% relative to the epidemiology of the disease.
3	41-60% the sum of all minority groups relative to the epidemiology of the disease and at least two minority groups reaching 60% relative to the epidemiology of the disease.
4	61-80% the sum of all minority groups relative to the epidemiology of the disease and at least three minority groups reaching 60% relative to the epidemiology of the disease.
5	80% the sum of all minority groups relative to the epidemiology of the disease and at least three minority groups reaching 80% relative to the epidemiology of the disease.

§: Studies will be ranked at the next lower rank if all criteria for next higher rank are not reached.

\*Minority groups in the US are self-defined by the participants and are listed as follows: African American or Black, Native American, Asian, Hispanic, and race. In other countries, minorities should be defined as appropriate, based on societal norms and internationally medically acceptable groups/nationalities.

## I: INDIVIDUAL PLAN; What is your SCORE?

- The modern Hippocratic oath begins with “I”
- Diversity can only be achieved when each individual team member and corporation embraces DEIA efforts.
- An individual’s diversity plan is central to this altruistic and self-preserving desire.
- The individual diversity plan should include:
  - To understand and address unconscious bias and develop strategies to overcome these issues in the immediate environment, community, and practice.
  - Implement a cultural competency plan with cultural humility and remove communication barriers. Cultural competency is defined as healthcare providers’ ability to function effectively in the context of cultural differences.
  - Self-education on the historical, structural, and systemic effects of racism, redlining, and economic factors precluding or preventing enrollment in clinical trials with their applicability to one’s community.
  - Develop a diverse workforce and research teams and enhance organizational DEIA plans.

## V: Verify

- Studies that meet the highest standards of diversity goals would be labeled as VERIFIED
- VERIFIED studies would be a focal point for presentations (ASH, ASCO, etc.) and a factor in new treatment approvals by the FDA or that country's regulatory body

## E: ELEVATE

- TEAM DIVERSITY enhances communication
- Establish Scholarships, grants and funding mechanisms to train minority/ diverse investigators and non-minority investigators practicing in minority communities
- Enhanced funding and training of potential investigators in historical Black colleges and medical schools
- Training should include physicians, advanced providers, nurses, social workers, pharmacists, navigators, medical assistants, students and other members of the clinical and research team



# FUTURE DIRECTIONS

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- Consensus recommendations:
- “Indianapolis Black Paper”
- Use Artificial Intelligence to evaluate clinical research data and ranking
- RANKINGS:
- I-RANK: Individual Investigator Diversity Rank Score
- RANK SCORE: Study Diversity Rank
- C-RANK (CORPORATE RANK): Corporate Aggregate Diversity Score
- VERIFICATION





*"I appeal to you to constantly bear in mind that not with politicians, not with Presidents, not with office-seekers but with you is the question: Shall the Union and shall the liberties of this country be preserved to the latest generations?"*

# What is Your SCORE?

**"Of all the forms of inequality, injustice in healthcare is the most shocking and inhumane."**

**Martin Luther King Jr.**

Convention of the Medical Committee for Human Rights in March 1966

**Life's most persistent and urgent question is, 'What are you doing for others?'**

**Martin Luther King Jr.**

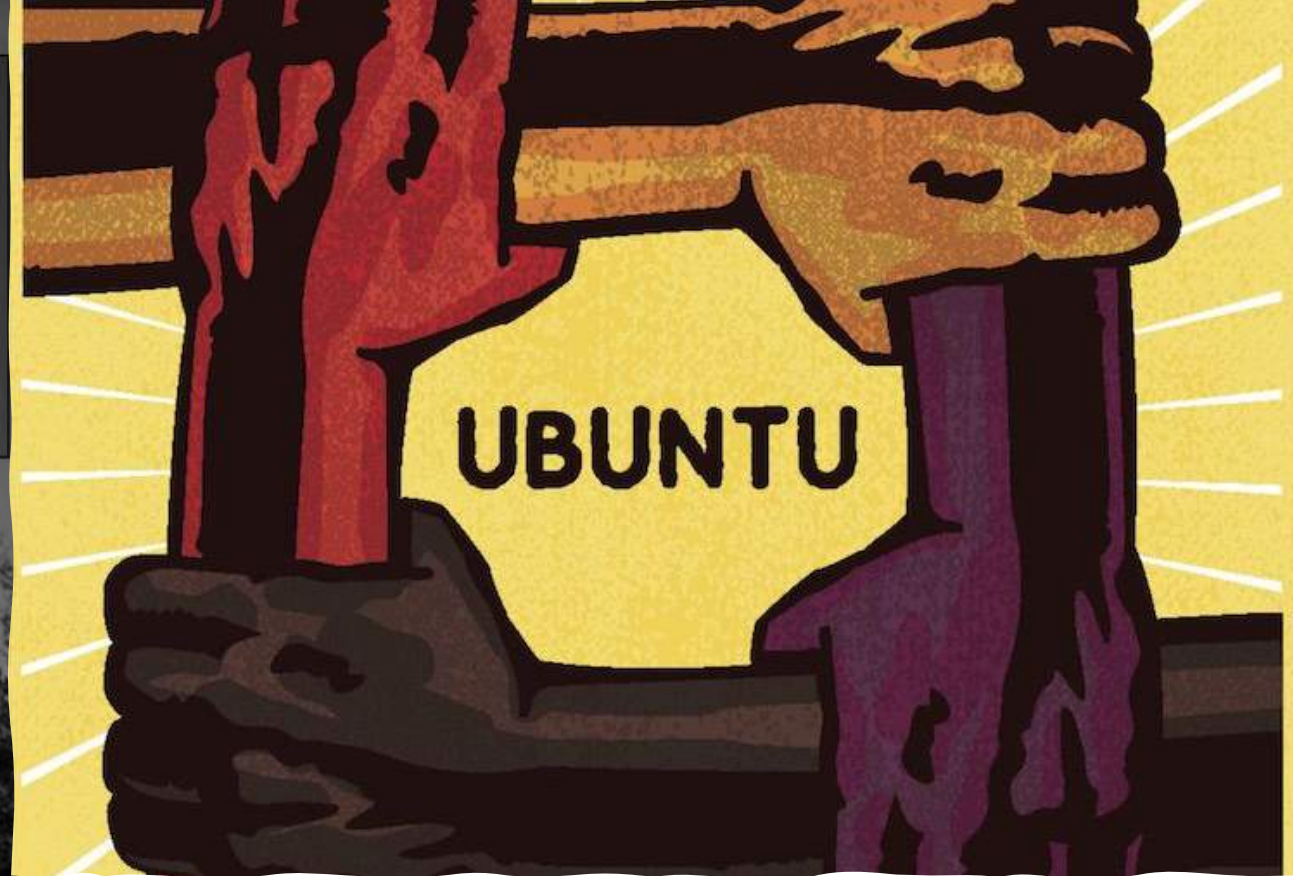
Montgomery, Alabama, March 1957



*"Give me your tired, your poor,  
Your huddled masses yearning  
to breathe free,  
The wretched refuse of your  
teeming shore.  
Send these, the homeless,  
tempest-tost to me,  
I lift my lamp beside the golden  
door!"*



*“Primum non nocere”*  
**First, do no harm!**  
- Hippocrates



HIPPOCRATIC OATH: “First do no harm”

UBUNTU: “I am because you are”

# Thank You

## #DRIVEwithFDORA



# Practical Strategies for Diversity, Equity, and Inclusion in Clinical Lymphoma Research



0 done

0 underway