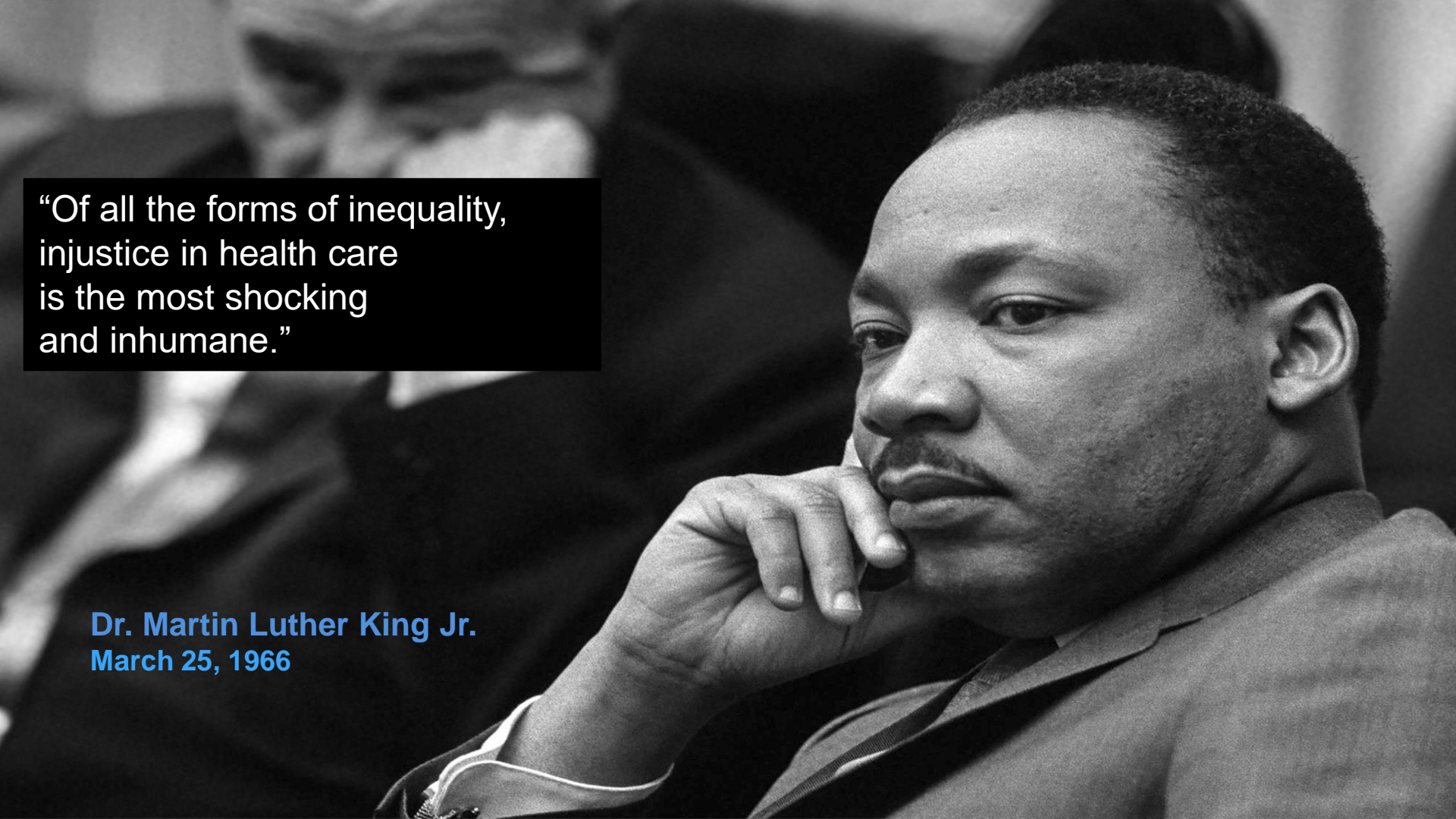


Advancing health equity by amplifying and embedding minority patient voices throughout research, development and healthcare

BEACON of HOPE - co-creating solutions to address the root causes of health inequity in US over 10 years

Patrice Matchaba, MD
Head Novartis US Corporate Responsibility &
President Novartis US Foundation

MassBIO Conference 21 July 2022

A black and white photograph of Dr. Martin Luther King Jr. He is shown from the chest up, wearing a suit and tie. He has a thoughtful expression, with his right hand resting against his chin and cheek. The background is blurred, showing other people in a crowd. On the left side of the image, there is a black rectangular box containing a quote in white text. In the bottom left corner, there is a caption in blue text.

“Of all the forms of inequality,
injustice in health care
is the most shocking
and inhumane.”

Dr. Martin Luther King Jr.
March 25, 1966

The COVID-19 Pandemic has highlighted the disproportionate and systemic health impact on communities of color in the US

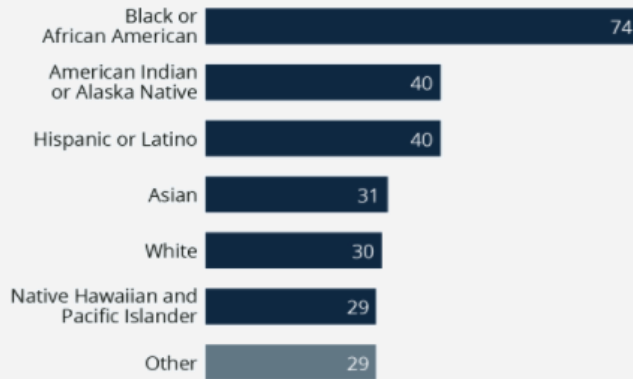


MARCH 22, 2020

SEAN FREEMAN: CORONAVIRUS

The Pandemic's Racial Disparity

Covid-19 deaths per 100,000 people in the U.S.
by race or ethnicity (as of July 30, 2020)



Source: The COVID Tracking Project



statista

The New York Times

U.S. Life Expectancy Plunged in 2020, Especially for Black and Hispanic Americans

The 18-month drop, the steepest decline since World War II, was fueled by the coronavirus pandemic.

Health disparities in the US based on race are not only unethical - but they also cost lives and waste resources

~USD 93bn in excess medical care costs, USD 42bn in lost productivity / year¹

In US, **40%** more black people have died from COVID-19 vs. white people²



1. American Public Health Association. 2. COVID Tracking Project and the Boston University Center for Antiracist Research, <https://covidtracking.com/race>



2021 Summary Statistics

January 1, 2021 - December 31, 2021

In 2021, CDER approved 50 novel drugs, either as new molecular entities (NMEs) under new drug applications (NDAs) or as new therapeutic biologics under biologics license applications (BLA). The 2021 annual report highlights demographic data from some novel therapeutics approved in the following categories:

- **Heart, Blood, Kidney, and Endocrine Diseases**
- **Autoimmune, Inflammatory, and Lung Diseases**
- **Infectious Diseases**
- **Neurological and Psychiatric Disorders**
- **Cancers**
- **Other Advances in Drug Therapies**

We hope information from this annual report will help promote further dialogue on how drug development can be enhanced to improve knowledge about the safety and effectiveness of therapies across the diverse patient community in the United States.

Heart, Blood, Kidney and Endocrine Diseases

In 2021, ten novel therapies were approved for medical conditions affecting the heart, blood, kidney, or endocrine system (Table 1).

Table 1. Summary of Demographic Data for Novel Therapies Approved to Treat Heart, Blood, Kidney, and Endocrine Diseases (numbers represent percentage of patients studied)

Indication	Female ¹	White ²	Black ²	Asian ²	Hispanic ²	≥ 65 yrs ⁴
To treat polycythemia vera*	39	98	0	0.6	NA	33
To mitigate chemotherapy-induced myelosuppression in small cell lung cancer	33	95	NA	NA	NA	47
To treat paroxysmal nocturnal hemoglobinuria*	61	61	3	15	NA	21
To treat homozygous familial hypercholesterolemia*	54	74	3	15	3	12
To reduce the risk of kidney and heart complications in chronic kidney disease associated with type 2 diabetes	30	63	5	25	15	58
To treat heterozygous familial hypercholesterolemia or clinical ASCVD	32	92	6	1	6	53

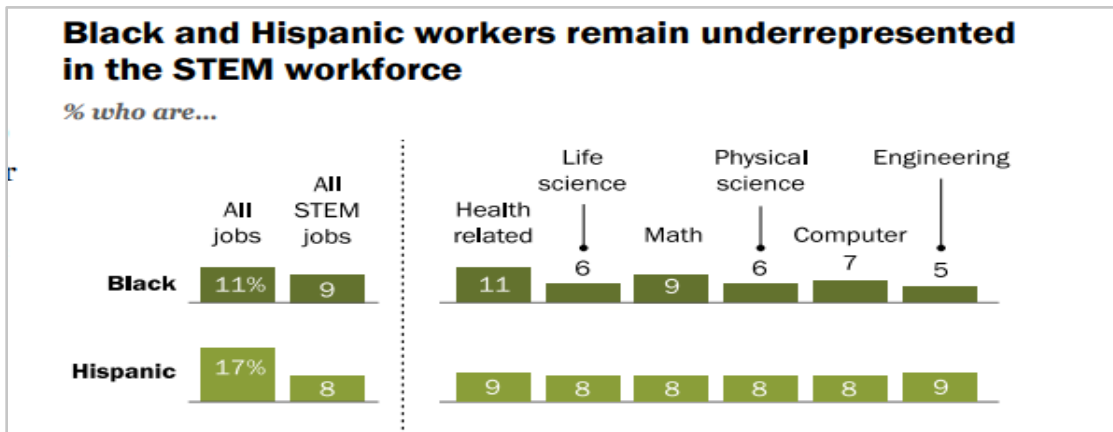
Indication	Female ¹	White ²	Black ²	Asian ²	Hispanic ²	≥ 65 yrs ⁴
To treat short stature due to inadequate secretion of endogenous growth hormone*	18	94	2	1	4	0
To mitigate the risk of cardiovascular death and hospitalization for chronic heart failure	24	64	5	22	16	63
To improve growth in children achondroplasia*	47	71	4	19	6	0
To treat severe hypoglycemia – adults	40	92	2	3	8	4
To treat severe hypoglycemia – pediatrics	52	94	NA	NA	17	0

NA – data not available | *Orphan disease | [Further explanation of footnotes click here](#)

We need to do a better job to increase not only patients and women of color in Clinical Trials but also Trial Investigators – from POC to Phase 3 Trials



- **Only 5 %of Doctors** identified as African American or Black (vs13.4% of population) and **less than 2% engaged** in Clinical trials



Trust and the past matters - Tuskegee, Henrietta Lacks and J. Marion Sims (the father of gynecology)



Herman Shaw, one of the last survivors of the Tuskegee study, raises his arms with praise as President Bill Clinton apologizes for the infamous experiment. (Susan Biddle/Washington Post)

The New York Times
Syphilis Victims in U.S. Study Went Untreated for 40 Years
 By JEAN HELLER
 The Associated Press

WASHINGTON, July 25—For 10 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its late effects, even though an effective therapy was eventually discovered.

The study was conducted to determine from autopsies what the disease does to the human body.

Officials of the health service who initiated the experiment have long since retired. Current officials, who say they

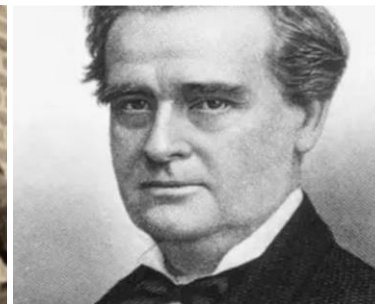
have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering what ever other medical services they can give to the survivors while the study of the disease' effects continues.

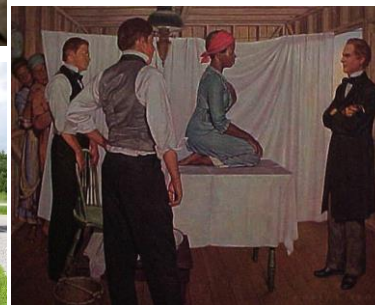
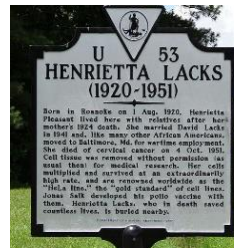
Dr. Merlin K. DuVal, Assant and Secretary of Health, Education and Welfare for Health and Scientific Affairs, expressed shock on learning o the study. He said that he wa making an immediate investigation.

The experiment, called the Tuskegee Study, began in 1932 with about 600 black men

500 x 653



Participants in the Tuskegee Syphilis Study, sourced via the National Archives and Record Administration on May 12, 2018. Photo Credit: Courtesy of the National Archives and Record Administration, 4956106



Racial bias and sexism are deeply embedded in how we practice medicine and deliver healthcare

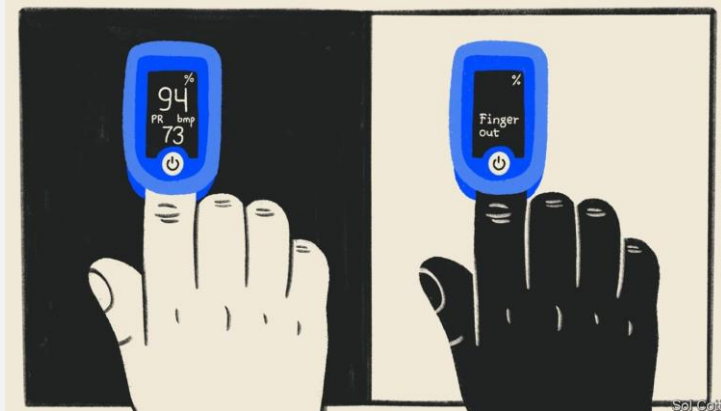
Science & technology
Apr 10th 2021 edition >

The Economist

Race and sex bias in medicine

How medicine discriminates against non-white people and women

Many devices and treatments work less well for them



Dr. Susan Moore, in a screenshot from a video she took while hospitalized with Covid-19.

 By John Eligon

Published Dec. 23, 2020 Updated Dec. 25, 2020

The New York Times

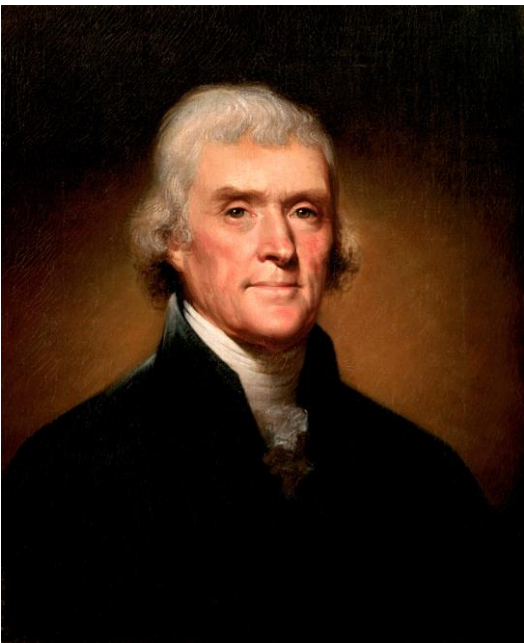
Why this matters – Case example of the negative health impact of using race in assessing kidney function



- Overestimation of renal function of African Americans using race and creatinine
- Late to be diagnosed with kidney failure
- Last on list for dialysis
- Last on list for kidney transplants

Race and sex-based data standards that have not been validated costs life's and need to be overhauled urgently.

Why this matters – another case example of lung function test “race correction” built into spirometers



Cotton Is King, and Pro-Slavery Arguments
S Cartwright, EN Elliot - 1860 - Pritchard, Abbott and Loomis

- Spirometers automatically factor in a 10% decrease in lung functions for African Americans as normal
- Therefore, they have to lose more lung capacity before diagnosis made
 - Delay in treatment
 - Less compensation in industrial/occupational exposure

Based on justification of race inferiority during slavery

Obstetrics

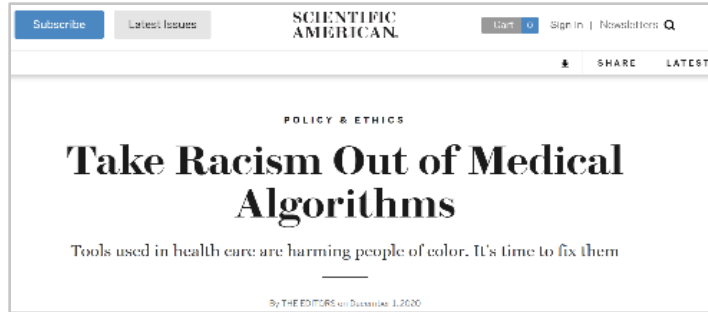


AA Film Archive / Alamy Stock Photo

- **Vaginal Birth After Cesarean – VBAC Risk Calculator**
- **Race - African American Women**
 - Bleeding risk increase
 - Anesthesia risk
 - Maternal Mortality

All Pictures Archive / Alamy Stock Photo

Why this matters – the integration of unvalidated “race correction” into the practice of medicine is deep and extensive



- NEJM Published more than 10 other serious diseases where race is imputed based on no evidence, to the detriment of African Americans
- This has a huge impact on individual patients and population health globally

After 4 months of intense discussion with African American communities and deans of Historically Black Medical Schools we learnt that :

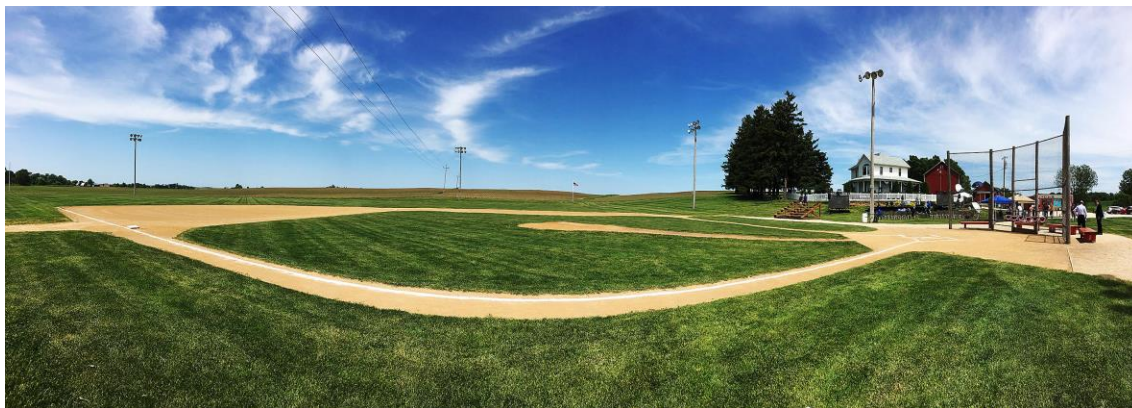
- **Developing Trust** by consulting and **co-creating the program** with the African American Community
- Address **STEM Education** and **generational wealth gap** – college fees are prohibitive
- Address **HBUCs underfunding** and lack of endowments
- Develop **Human Capital** and knowledge transfer about R&D
- Health Inequity is complex and “**a system-based approach is best suited**”

It will take time

Health Inequity in the US today is a result of centuries on inequity across every walk of life



If you build it they will come



ZUMA Press, Inc. / Alamy Stock Photo



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“And they did come”



Alabama A&M University



Bowling State University



Charles R. Drew
University of Medicine &
Science



Howard University



Howard College of
Medicine



Jackson State University



North Carolina A&T State
University



Prairie View A&M
University



Southern University and
A&M College



Clark Atlanta University



Delaware State
University



Dillard University



LeMoyn-Owen College



Lincoln University of
Pennsylvania



Meharry Medical School



Spelman College



Tennessee State
University



Texas Southern
University



Fisk University



Florida A&M University



Hampton University



Morehouse College



Morehouse School of
Medicine



Morgan State University



Tuskegee University



University of Maryland
Eastern Shore



Xavier University of
Louisiana



A Historic PLEDGE called the Beacon of Hope to address the systemic causes of Health Inequity impacting African Americans and Hispanics : July 2021

We believe that through concerted action we can deliver measurable impact. Moreover, we hope that through our efforts we can help to enlist others to this cause, including other biotechnology and pharmaceutical companies who share the same vision and objectives. Upon signature of this pledge, as a first step toward our planned 10-year collaboration, our goal is to spend the next 6 months co-creating potential solutions with the communities we aim most to impact, for we are united in our mission to positively bend the curve of life for all.

MEDIA & INVESTOR RELEASE

Novartis pledges 10-year commitment with Morehouse School of Medicine, 26 Historically Black Colleges, Universities, Medical Schools and other leading organizations to co-create effective, measurable solutions for health equity

- *Novartis and the Novartis US Foundation to join forces with Thurgood Marshall College Fund, Morehouse School of Medicine, 26 other Historically Black Colleges, Universities and Medical Schools and others to address root causes of disparities in health and education*
- *This collaboration will create actionable solutions to target the systemic racism that drives inequitable health outcomes and work together for health equity progress through greater diversity, equity and inclusion across the research and development ecosystem*
- *Novartis US Foundation plans to invest approximately \$13.7 million to establish three digitally enabled research centers at Morehouse School of Medicine, including a clinical trial center of excellence that could be a model for possible*



Vas Narasimhan, M.D.
Chief Executive Officer
Novartis



Patrice Matchaba MD
President Novartis US
Foundation & Head of
Novartis US Corporate
Responsibility



Dr. Valerie Montgomery
Rice
President
Morehouse School
of Medicine



Dr. Harry L. Williams
President & CEO
Thurgood Marshall
College Fund



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Executive Director
National Medical
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Jeff Maggioncalda
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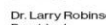
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Charles Drew University
of Medicine and Science



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Dr. Harold Martin
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University



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Prairie View A&M
University



Dr. Charlotte P. Morris
Interim President
Tuskegee University



Dr. Heidi Anderson
President
University of Maryland
Eastern Shore



Dr. Reynold Verret
President
Xavier University
of Louisiana

Beacon of Hope: 10-year faculty support to run Centers of Excellence for Clinical Trials in the Four Historically Black Medical Schools – starting at Morehouse School of Medicine



Valerie Montgomery Rice, MD,
FACOG

President and CEO, Morehouse School of Medicine

Center of Excellence for Clinical
Trials

Center of Excellence for Climate,
Environment and Health

Center of Excellence to Review the
use of “Race Correction in Medicine”

Beacon of Hope - addressing generational wealth, STEM and research gaps over 10 years

- **1200 Students** Novartis Mentoring to prepare them for careers in Industry and Research and Development
- **340 Scholarships** for students
- **90 HBCU Faculty Research Grants**



Harry L. Williams
President and CEO
Thurgood Marshall College Fund

TMCF-Novartis US Foundation HBCU Alliance Announce Faculty Grant Winners

\$2.25 million will be granted over 10 years to HBCU
faculty at select institutions

June 21, 2022 16:25 ET | Source: Thurgood Marshall College Fund

NOVARTIS US FOUNDATION FACULTY GRANT
rtis Faculty Grant Announcements (1)
Dr. Keshia Baptiste-Roberts
Morgan State University

NOVARTIS US FOUNDATION FACULTY GRANT
rtis Faculty Grant Announcements (1)
Dr. Dorothy Dillard
Delaware State University

NOVARTIS US FOUNDATION FACULTY GRANT
rtis Faculty Grant Announcements (1)
Dr. Ebony Weems
Alabama State University

NOVARTIS US FOUNDATION FACULTY GRANT
rtis Faculty Grant Announcements (1)
Dr. Tiffany Williams
Tennessee State University

NOVARTIS US FOUNDATION FACULTY GRANT
rtis Faculty Grant Announcements (1)
Dr. Janeese Brownlow
Tennessee State University

NOVARTIS US FOUNDATION FACULTY GRANT
rtis Faculty Grant Announcements (1)
Dr. Brenda Batts
Delaware State University

NOVARTIS US FOUNDATION FACULTY GRANT
rtis Faculty Grant Announcements (1)
Dr. Shelley Johnson
Florida State University

NOVARTIS US FOUNDATION FACULTY GRANT
rtis Faculty Grant Announcements (1)
Dr. Moushumi Roy
Hampton University



TMCF – Novartis Foundation Alliance Scholarships winners : first group of 120 students to be announced next month



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Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups (2022)

DETAILS

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CONTRIBUTORS

Kirsten Bibbins-Domingo and Alex Helman, Editors; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research; Committee on Women in Science, Engineering, and Medicine; Policy and Global Affairs; National Academies of Sciences, Engineering, and Medicine

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Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE/CDER) Lois Fashoyin-Aje, 240-402-0205, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or CDERClinicalEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Minority Health and Health Equity (OMHHE)

[Date]
Clinical Medical

June 22, 2022 Expansion of Beacon Of Hope Partnership

Novartis expands Beacon of Hope through alliances with Historically Black Medical Schools to address systemic health disparities

[Back to News Archive](#)

Jun 22, 2022

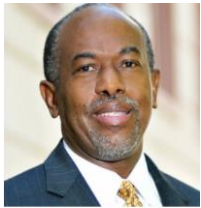


ARTICLE | PRODUCT DEVELOPMENT

Novartis expands partnership with HBCUs, adds Sanofi and Merck

Beacon of Hope aims to address racial health disparities by increasing diversity among clinical trial participants and investigators

BY KAREN TKACH TUZMAN, SENIOR EDITOR
June 22, 2022 9:16 PM EDT



James E.K. Hildreth, M.D.



Charles R. Drew University
of Medicine and Science





Which diseases your research and develop medicines for also matters and is core to DEI in Science



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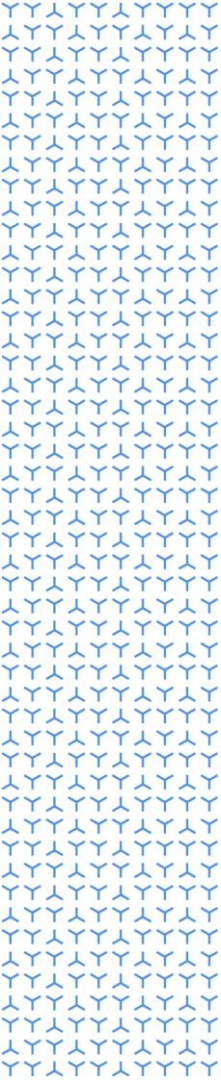
**March 13, 1946
– May 7, 2022**



***“IT ALWAYS SEEMS IMPOSSIBLE
UNTIL IT IS DONE”***

NELSON MANDELA

PRISONER #46664



Thank you