

## Agenda

1:00 -1:10 pm	Welcome & Introductions Jennifer Covich Bordenick, Chief Executive Officer, eHealth Initiative & Foundation
1:10 -1:20 pm	Research from Studies That Reveals How SDOH May Have an Impact on Clinical Trials Luther T. Clark, MD, FACC, FACP, Deputy Chief Patient Officer, Merck
1:20 -1:30 pm	The Implications of Clinical Trials Without Diversity, Equity, or Inclusion Lili Valletta, CEO and Co-founder, CIEN +   CulturIntel
1:30 -1:40 pm	Current Pharma-Led Initiatives Around Health Equity and Diversity In Clinical Trials Lorena Kuri, Head, Diversity Strategy, Bristol-Myers Squibb
1:40 -1:50 pm	Removing Barriers to Patient Access to Clinical Trials  Dana Dornsife, Founder and CEO, Lazarex Cancer Foundation
1:50 -2:05 pm 2:05 -2:15 pm	Panel Discussion Closing Thoughts



## **Our Work**







Privacy Policy
Comment Letters

Policy Steering Committee (PSC)
Capitol Hill Briefings
HHS, FTC, OCR, Relationships
Hill Meetings



Expert Roundtables

Advisory Boards,
Workgroups

Grants/ Partnerships

HHS, FTC, OCR,
Relationships

Surveys, Reports

Expert Faculty



#### **eHealth Initiative Members**



























BlueCross BlueShield Association

































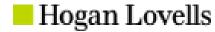
























































































## **Current Critical Issue Areas**



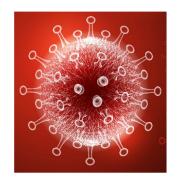
Consumer Privacy for Health Data



**Virtual Care** 



Analytics, Social
Determinants of
Health (SDOH) &
Artificial Intelligence



COVID-19 Best Practices & Education



## Recent Forums & Webinars

#### COVID-19

- Rapidly Deployed Remote Monitoring for COVID-19
- COVID-19 and Beyond: Telepsychiatry Best Practices and Regulatory Priorities
- Fitbit Talks About Population Health Initiative During COVID-19 Pandemic
- How the Pandemic Influences Consumer Health Behavior
- After the Curve Flattens: What's Next for Healthcare and COVID-19

#### **Telehealth & Policy**

- Addressing Capacity and Cashflow with Virtual Care
- How to Grow Your Practice with Reimbursement Considerations
- Telehealth during COVID-19: New Strategies on How Physicians are Addressing the Outbreak

#### **Privacy**

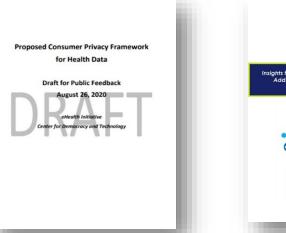
- What's Ahead in 2020 for Consumer Privacy?
- HIPAA: What's Covered and What's Not Covered?
- Changes to Privacy Policies and Regulations in the Face of the Coronavirus Pandemic - eHI Privacy and Security Webinar Series
- Key Survey Findings from the State of Patient Matching in America

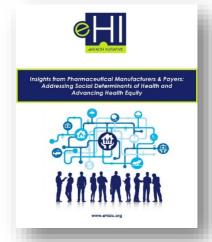


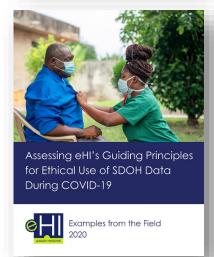
## 2020 Publications

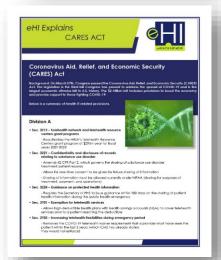


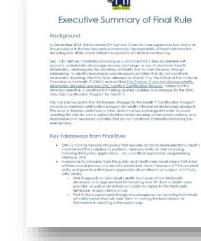
















## **Upcoming Forums & Webinars**

January 20<sup>th</sup>: New Strategies for Patient Engagement: Lessons Learned During the Pandemic

January 26-28th: eHI Annual Member Meeting

February 3<sup>rd</sup>: How Providers are Scaling Virtual Care: Best Practices and Lessons Learned from the Leaders

For a full list of virtual events:

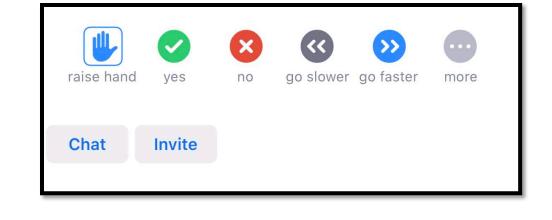
https://www.ehidc.org/events





## Housekeeping





- Submit your questions in the Q&A box
- We will answer as many question as time allows and follow up the unanswered questions
- Use the chat box is for technical difficulties and other questions / comments



## Thank You to the Sponsors





#### **Panelists**



Jen Covich Bordenick CEO eHealth Initiative and Foundation



Luther T Clark, MD, FACC, FACP Deputy Chief Patient Officer & Global Director Merck



Lili Gil Valletta Co-Founder and CEO CIEN+ and CulturIntel



Lorena Kuri
Diversity Strategy |
Global Clinical Trial
Planning & Alliances
Bristol-Myers Squibb



Dana Dornsife
Founder and CEO
Lazarex Cancer
Foundation





# Impact of Social Determinants of Health on Clinical Trial Participation & Diversity

Luther T. Clark, MD

**Deputy Chief Patient Officer** 

Merck

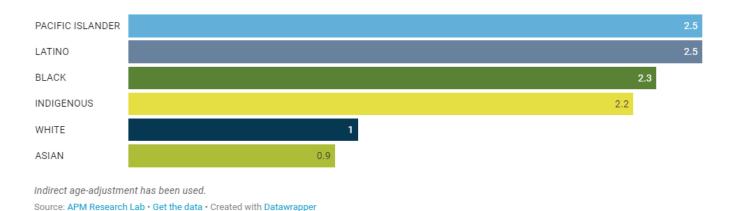
January 12, 2021

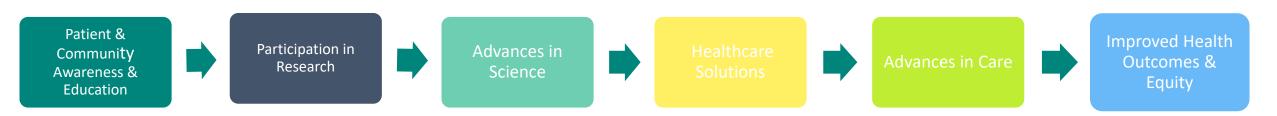
#### COVID-19: disparities, inequities, clinical trial diversity

COVID-19 Pandemic and clinical trials have highlighted longstanding healthcare disparities and amplified importance of participation of impacted communities in research and development of healthcare solutions

### Adjusted for age, other racial groups are this many times more likely to have died of COVID-19 than White Americans

Reflects mortality rates calculated through Jan. 5, 2021.





#### Participant barriers to clinical trial diversity

#### Mistrust

Fear

Lack of comfort with process

Logistical constraints such as time, outof-pocket expenses, transportation, etc

Lack of Awareness and/or information about clinical trials

Social determinants of health

- SDOH (i.e., education, economic stability, neighborhood, health and health care access, social and community context) may negatively impact the decision of patients to participate in clinical research
- Recognition/understanding the SDOH may help address and overcome barriers to participant diversity and improve the development of healthcare solutions and patient outcomes



## Social and economic conditions can negatively impact willingness and ability to participate in research



Economic stability (income, employment, debt, expenses, etc.)

Racial and ethnic minorities experience higher economic instability. Implicit costs (transportation, childcare, parking, loss of income from missing work) can lead to low participation



Education (literacy, linguistic fluency, vocational training, and higher education)

Individuals with low levels of education may find information about research trials and informed consent to be complex and difficult to comprehend.



Neighborhood and built environment (transportation, safe/modern housing, sidewalks, etc.)

An individual's environment (transportation, access to health care and research sites) may limit ability to participate in research studies.



Health and health care (availability of health coverage/specialist HCP, QOC, cultural competency)

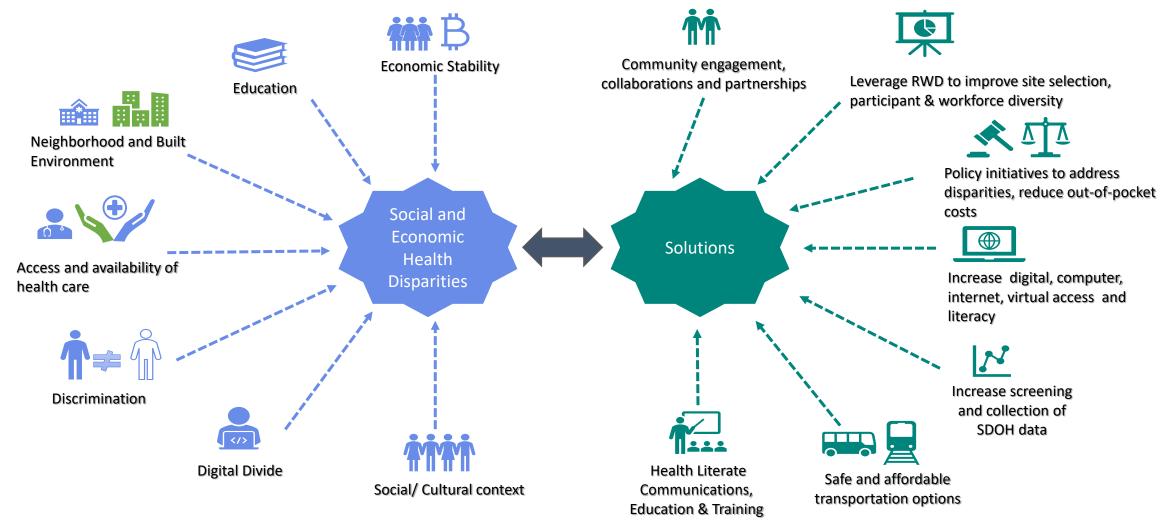
Access to care, quality of care, and insurance coverage have been giver as reasons for some patients' refusal to participate in research studies.



Social and community context (social integration, community engagement, trust, and social support)

Discrimination and exploitation of minority communities has led to nistrust and suspicion of healthcare systems and research.

## Recognizing and addressing SDOH to increase clinical trial diversity



## Patient and community engagement support diverse participation

Forming Relationships

Sustained partnerships

Training and Support

**Shared Goals** 

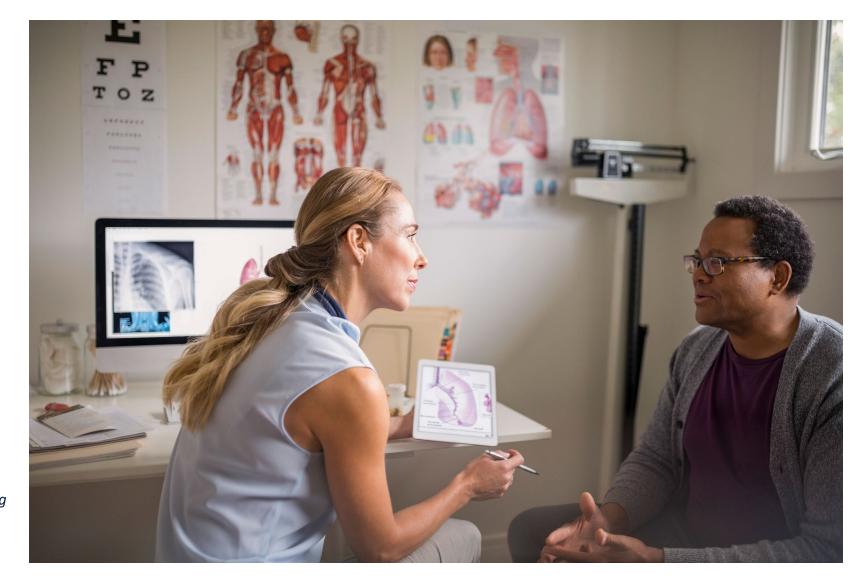


**Build Trust** 



#### **Summary**

- Achieving diversity, inclusion & health equity in clinical research and across the spectrum of care needs to be prioritized.
- Recognition/understanding the SDOH may help address and overcome barriers to minority participation in research and improve the development of healthcare solutions and patient outcomes
- Community partnerships and collaborations play critical roles in achieving effective and sustainable success. Insights about what matters to patients and their communities are especially helpful for increasing awareness, education and building trust.

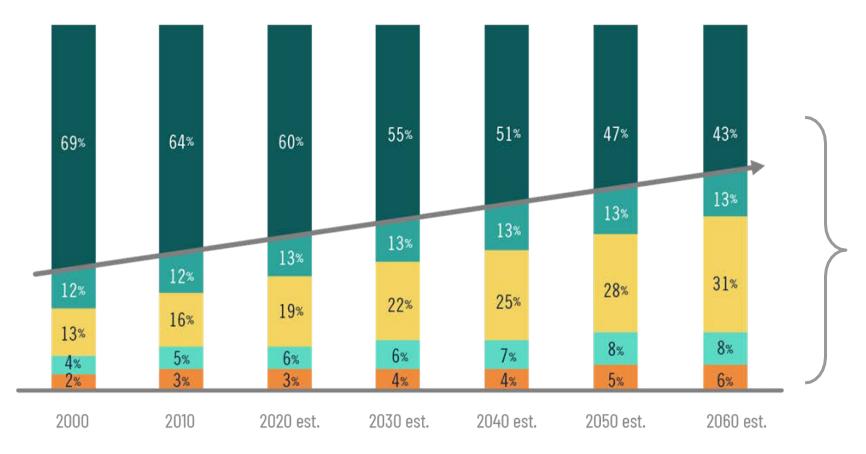




#### 4KEY

# TRENDS TO CONSIDER

# #1 SIZE & GROWTH: Fast approaching majority-minority nation by 2040



10%

U.S. POPULATION

CROWIH[NEW PATIENT

CROWIH]IS DRIVENBY

MULTICULTURAL

SEGMENTS.

Hispanics are the largest segment contributing with 50%+of overall population growth.

#### **U.S. POPULATION**



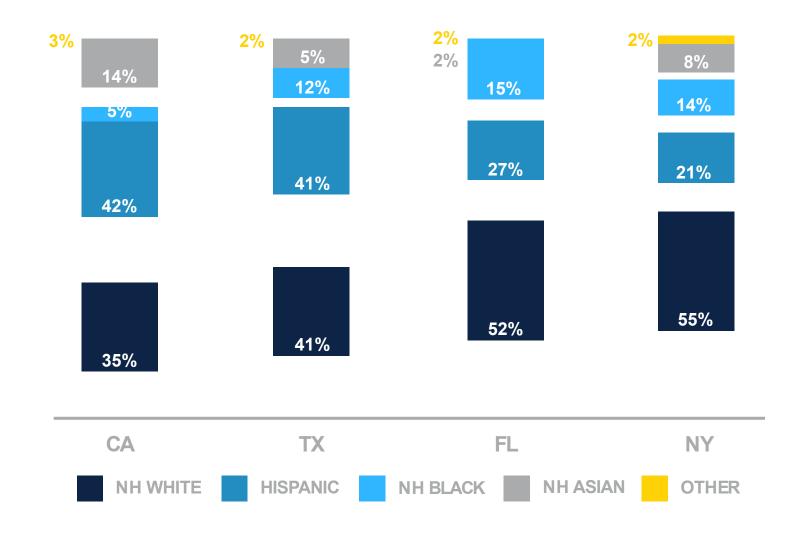
#### DIVERSITY ACROSS TOP 4 MOST POPULOUS STATES

STATES WITH LARGEST POPULATION IN THE U.S. (2019)



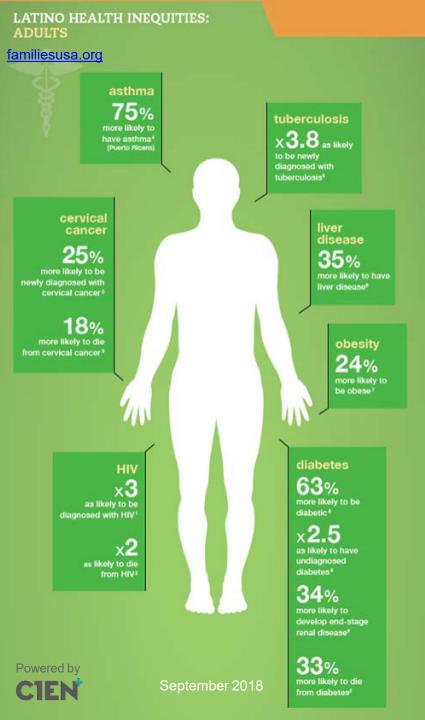
ACROSS THE LARGEST STATES IN THE U.S. AND SOME DMA'S WE HAVE ALREADY REACHED MAJORITY-MINORITY

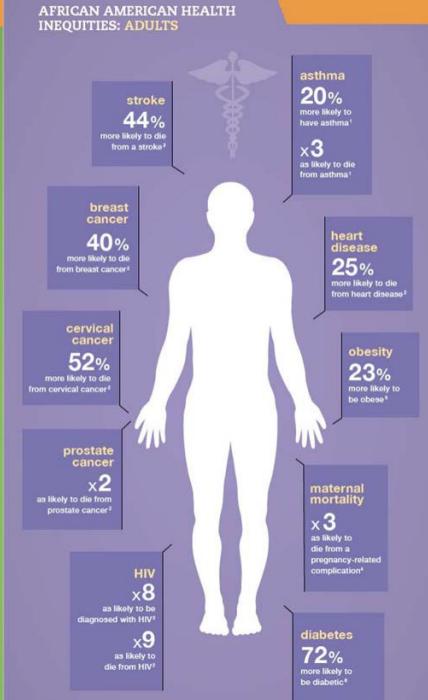
CA+TX alone represent 47% of the total U.S. Latino population



Source: U.S. Census / Geoscape 2019







#2

High growth diverse segments are disproportionately affected by chronic diseases

Source: LATINO HEALTH INEQUITIES COMPARED TO NON-HISPANIC WHITES

## #3

## VALUE-BASED: A reimbursement model shift from volume-based to value-based solutions



Value-Based Contracts with Risk 3 to 5 Years Away for Providers

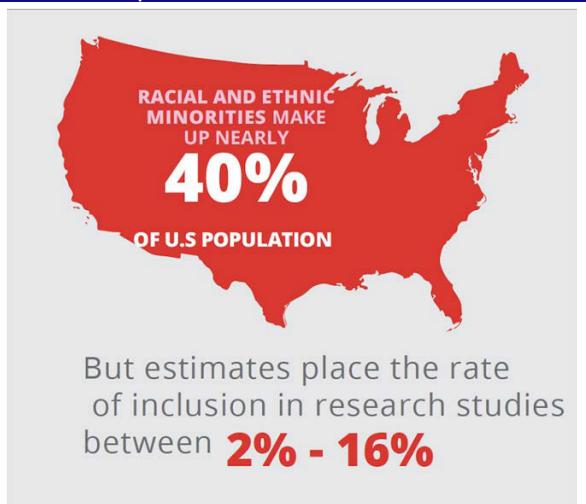


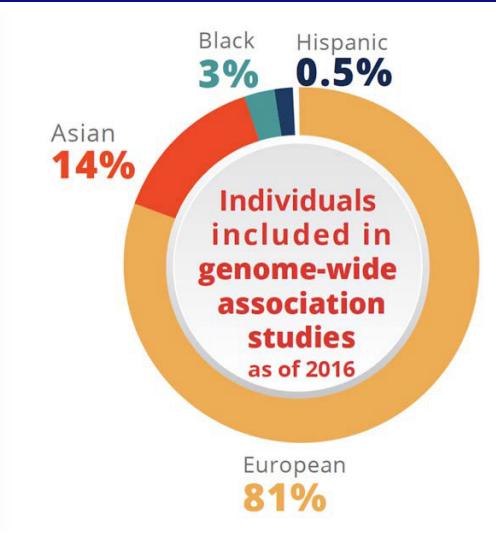
# How Has COVID-19 Impacted the Value-Based Care Movement?

A new, wide-ranging report on value-based care looks at COVID-19's role in accelerating the movement, and what the near-term outlook is for industry stakeholders



## #4 Lack of clinical trial diversity compromises the promise of personalized medicine









## Fewer than 5% of breast cancer studies were stratified by race and socioeconomic factors

By utilizing data derived from a primarily white study group, scientists ignore the impact of cancer drug efficacy on the other 3 major race groups which may prove detrimental to survival rates.

Powered by CIEN

International Journal of Public Health (2019) 64:1255-1256 https://doi.org/10.1007/s00038-019-01293-2

#### EDITORIAL





## The personalized medicine challenge: shifting to population health

Kimberly Alba Mc Cord oo

Received: 13 December 2018/Revised: 31 July 2019/Accepted: 24 August 2019/Published online: 30 August 2019

Personalized medicine (PM) is an initiation

en when current PM analyses are enough to complement evidence als, the decision to collect large (e.g., on tumor receptors and their treatments) instead of extracting RWD and then deriving specific ght be limiting and unsustainable the field through inductive rea-

n-wide data and develop theories medicine. We could strengthen and use population health outh hypothesis applicable at the focusing on improving the outnd directing hypothesis-testing ple, an electronic health record Button (Longhurst et al. 2014), rts and screen for elements the physicians care for patients y represented in clinical trials, on to search for other patients

and recommend a course of ...... combined records. We should create large RWD networks and use this vast information to answer PM questions, not the other way around.

Using RWD also lowers the risk that PM will fall into the health disparity trap. PM is driven by monetary forces such as the research agenda of pharmaceutical companies, rather than research needs, but this bias could be reduced by strengthening the population precision medicine infrastructure and leveraging RWD. In such a scenario, point-of-care trials, virtual trials, or other study designs of more pragmatic nature can be implemented in healthcare systems and more likely be initiated by investigators rather

heavy, and rules a local ollecting and maintaining data may Personalized medicine has its limits...It is time that we shift our focus to personalized population medicine and integrate elements other than omics into personalized health, including social, environmental, and behavioral causal factors of disease development.

> to recognize patterns after being trained on large datasets. Low quality data, including misclassification and formatting issues, may derail these efforts, especially in healthcare where data acquisition is burdensome, collected data are often unstructured and text-

This Editorial is part of the series "Young Researcher Editorial", a training project of the Swiss School of Public Health (SSPH+).

Nimberly Alba Mc Cond.

#### COVID-19 ACCELERATION AND THE RACE TO A VACCINE

RACE FOR A CURE OCTOBER 6, 2020 / 7:04 AM / UPDATED 3 MONTHS AGO



# Exclusive: Moderna vaccine trial contractors fail to enroll enough minorities, prompting slowdown

# Covid-19: lack of diversity threatens to undermine vaccine trials, experts warn

Oxford and Moderna trials draw from strikingly white cohort, for a virus that has disproportionately affected people of colour

The lack of diversity proves problematic as COVID-19 has been found to infect Black Americans almost three times more than white Americans, and Black Americans are twice as likely to die from the coronavirus, Reuters reported, citing multiple studies.

"I would rather we have higher diverse participants and take one extra week," Moderna CEO Stephane Bancel said. Diversity "matters more to us than speed."





#### BARRIERS TO CLINICAL TRIALS PARTICIPATION BY SEGMENT CULTURINTEL'S ANALYSIS OF 372K DIGITAL DISCUSSIONS



#### **OVERALL** N=372K

#### **BLACKAMERICANS** N=30K

**HISPANICS** N=19K



Lackof awareness 38%



concerns 27%









Lackof awareness 24%







Fear & anxietv21%





Costs 10%



**Application** process 17%







**Application** process 10%



Costs 11%



**HCP** concerns 27%



**Application** process 23%



Costs 22%



3X vs. overall



Lackof awareness 19%



Fear & anxiety 9%

#### **NOT A ONE** SIZE FITS ALL

The biggest barriers to clinical trials for both African Americans and Hispanics are

- 1. Trust issue towards the HCP involved in the clinical trial
- 1. The difficulty of the application process
- 1. The anticipated **costs**

Beyond lack of awareness and fear/anxiety, top 2 barriers for overall.

## UNLOCK THE POWER OF

# Cultural Intelligence

The ability to be aware of, understand and apply cultural competence and inclusive data into everyday business.

#### **PERSONALIZATION**

### **AT SCALE**

INSIGHTS
TRIAL DESIGN
CLINICAL DATA
RWE
COMMERCIAL
INDICATIONS
DIFFERENTIATION
VALUE-BASED
CONTRACTING





#### WE NEED HEROES...

of all ages, ethnicities

and genders, to step up and

be counted on and counted in

CLINICAL TRIALS.

To bring a vaccine that works

for ALL.





## Diversity in Clinical Trials #DCT

## The Need for greater DIVERSITY in Clinical Trials

Bristol Myers Squibb<sup>™</sup> Division/Therapeutic Area Highly Confidential

## Agenda

The concept of Diversity

Why Diversity in Clinical Trials is an enterprise priority

How Bristol Myers Squibb is addressing this important topic and Diversity Goals

A case study: prostate cancer in the Black American population

Bristol Myers Squibb Division/Therapeutic Area

## Understanding the Global Nature of Diversity





















Bristol Myers Squibb Division/Therape

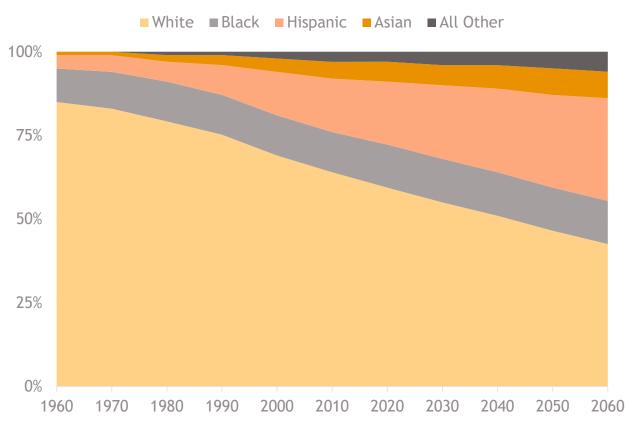
Division/Therapeutic Area Highly Confidential

### America's racial and ethnic tapestry is changing

• Race is ascribed to individuals on the basis of physical traits while ethnicity is more frequently chosen by the individual

• Ethnicity encompasses everything from language, nationality, culture and religion, and can enable people to take on several identities



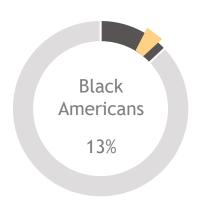


LifeScience Magazine, February 2020

Source: The Next America, PEW Research, 2014 - updated

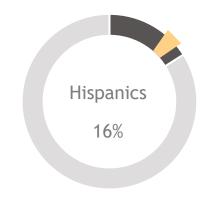
## Impact of race and ethnicity on clinical trials

Clinical trials conducted today in the US lean heavily toward patient participant populations that are 80% white



Black Americans represent 13% of the US population but only ~4% participate in clinical trials

Total U.S. population



Hispanics represent 16% of the US population but only ~3% participate in clinical trials

Asian Americans 6%

Asian Americans represent 6% of the US population but only ~3% participate in clinical trials

% of race within U.S. population % participation of race in CT

Source: 2019 Quick Facts US Census <a href="https://www.census.gov/quickfacts/fact/table/US#">https://www.census.gov/quickfacts/fact/table/US#</a>
Adapted from FDA Drug Trials Snapshots Summary Report 2015 - 2019

Bristol Myers Squibb

Division/Therapeutic Area

## Potential Barriers to Clinical Trial Participation

## Sponsors

- Variable understanding of what the patient needs to participate: impact to daily life
- Limited interest in inexperienced sites and investigators
- Lack of direct communication to sites about the need and importance of clinical trial diversity

## Clinical trials research sites

- · Lack of diverse investigators and research staff
- Site start up costs are expensive
- Lack of referral to trials (bias) or lack of community engagement
- Inexperienced research sites that have ongoing research but may overlook a diverse population

# Patients and caregivers

- Practical obstacles to participation: transportation, childcare, lack of insurance
- Lack of trust in pharma and medical research
- Low health literacy, not limited to language barriers
- Lack of awareness of clinical trials
- · Lack of research savvy clinicians within healthcare facilities

# Societal Factors

- Qualified subjects are not always offered the opportunity to participate
- Socio-economic burdens to the participant can be overlooked: cost of transport, childcare, cost of missing work

## Diversity in Clinical Trials #DCT

# How is BMS addressing this important topic

Bristol Myers Squibb Division/Therapeutic Area Highly Confidential

## R&D Diversity in Clinical Trials Objective & Goals

## **Objective**

To improve recruitment of diverse patients in our clinical trials, ensuring that the population is more reflective of the real world population

## Foundational Approaches

- Align with formal BMS Sustainability objectives and enterprise Health Equity initiative
- Leverage strong D&I culture,
   broaden participation through PBRGs
- Anchor activities in formal processes and long-term ways of working, strive for "permanence"

## **Projected Outcomes**

Increased opportunity of clinical trials for diverse patients

Accelerated innovation and development of transformative medicines in support of company sustainability goals

Reinforced culture of diversity & inclusion, together with our PBRGs

Alignment with increased health authority focus and requests

## Diversity in Clinical Trials #DCT areas of focus



# Awareness & Communication

Establish a clear plan for communication of progress



## Clinical Trial Data

Consider study design aspects which impact diverse patient populations



## Patient & Caregiverfacing Materials

Create focused clinical trial materials targeted to specific populations



## Site Selection

Develop strategy aligned w/ the epidemiology of disease or condition being studies

## Diversity in Clinical Trials #DCT

# Case Study

Bristol Myers Squibb Division/Therapeutic Area

Highly Confidential

# Driving Increased Enrollment of Black Patients in Prostate Cancer Trials

The incidence of prostate cancer is about 60% higher in Blacks than Whites for reasons that remain unclear<sup>1</sup>

#### Tactics to Drive Diverse Patient Recruitment:

- Collaboration with advocacy and community based organizations to generate awareness about prostate cancer and clinical trials
- Targeted site selection in areas with increased black population

#### Other benefits:

- Increased interest in clinical trials among black men
- Enhanced study design based on advice from Advocacy Organizations

### Building on this model for the future:

- Consistent application in future prostate studies
- Communicate diversity strategy at Investigator Meetings
- Develop culturally appropriate materials

Black
patients
enrolled in
prostate
clinical trials
in US<sup>2</sup>

4%

Black patients enrolled in the US in 9KD trial

17.7%

# Thank you







### THE BARRIERS

LACK OF KNOWLEDGE



FINANCIAL CONSTRAINTS



SUPPORT NETWORK INTERRUPTION





HISTORY

HISTORICAL



CULTURAL /
LANGUAGE



**SOCIOECONOMIC** 



At the age of 4, Nevaeh was diagnosed with Stage IV

High Risk Neuroblastoma Cancer. She has been in

clinical trial treatment for almost 4 years. Amazingly

it was the cost of a tank of gas every other week

that was preventing her Mom from being able

to take her to her life saving clinical trial.



Nevaeh, 34 months



Unstructured
Nationwide Focus
Clinical Trial Navigation
Travel Expense Reimbursement
Community O & E
Patient Self Referral
Increased Enrollment & Diversity
Equitable Access









Highly Structured
Geographic Focus
Assess Social Determinants of Cancer
Identify & Characterize Cancer Disparities
(Incidence, Prevalence, Risk, Mortality)
Gateway into At-Risk Communities
Create Baseline & Action Strategy
Place Based & Community Led
Culturally Appropriate
Improved Cancer Health Outcomes
Equitable Access







Institutional Focus
Action Specific
Health Professional Referral
during TCT Consent
Travel Expense Reimbursement
Community O & E
Increased Enrollment & Diversity
Equitable Access







## **Care** Navigation & Reimbursement Process







Apply for Reimbursement



**Determine Eligibility Level** 







Reimburse Monthly

Increased Enrollment & Diversity - Equitable Access!



## The Community IMPACT Process



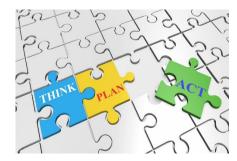
**Identify Location** 



**Create Team** 



**Conduct Assessment** 



Form Action Plan



**Engage with Community** 



Measure Results

Addressing Health Disparities and Improving Outcomes!







## Results

EHTNICITY DATA										
	CARE January 2015 - August 2020			CARE		IMPACT				
				January 2018	to August 2020	January 2018 to August 2020				
Race / Ehtnicity	Number of Patients	Percentage		Number of Patients	Percentage	Number of Patients	Percentage			
American/ Alaskan Indian	0	0%		0	0%	2	1%			
Asian/Pacific Islander	58	4%		18	3%	51	14%			
Black/African American	130	8%		65	10%	16	4%			
Latino/Hispanic	190	12%		53	8%	153	42%			
Multi-Ethnic	12	1%		8	1%	5	1%			
White	1171	75%		491	77%	136	38%			
Sub-Total	1561	100%		635	100%	363	100%			
Unspecified	53			20		14				
Total	1614			655		377				
	25% Minority Participation			23% Minority	/ Particpation	63% Minority Particpation				







## Results

HOUSEHOLD INCOME DATA										
	CARE January, 2015 - August 2020			CA	\RE	IMPACT				
				January 2018 to August 2020		January 2018 to August 2020				
Income Range	Number of Patients	Percentage		Number of Patients	Percentage	Number of Patients	Percentage			
Less than \$15,000	287	18%		98	15%	130	34%			
\$15,000 - \$24,999	207	13%		68	10%	66	18%			
\$25,000 - \$34,999	191	12%		78	12%	33	9%			
\$35,000 - \$49,999	259	16%		104	16%	34	9%			
\$50,000 - \$74,999	308	19%		139	21%	49	13%			
\$75,000 - \$99,999	215	13%		96	15%	34	9%			
More than \$100,000	147	9%		72	11%	31	8%			
Total	1614	100%		655	100%	377	66%			
	31% Income less than 25K			25% Income less than 25K		52% Income less than 25K				

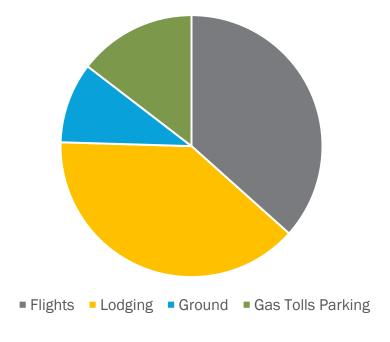




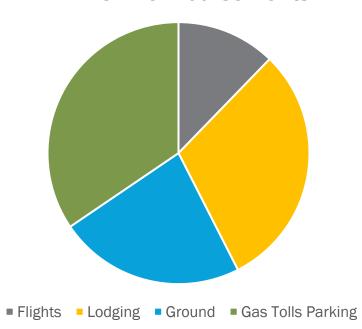


## Results

### Care Reimbursements



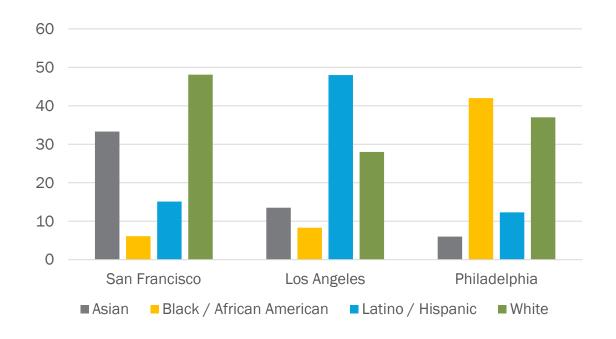
### **IMPACT** Reimbursements





### **Catchment Area Variation**

### Racial / Ethnic Diversity Dependent upon Local Catchment Areas





### Conclusion

While racial/ethnic diversity will be dependent upon local catchment areas, both Care and IMPACT data support the conclusion that universal implementation of a financial reimbursement program for travel costs is fundamental to removing a significant barrier to equitable access and increasing cancer clinical trial diversity.

We would like to thank everyone at UCSF and USC Norris for their participation in the IMPACT program and all the patients who continue to fight their battle with cancer on the frontlines of cancer clinical trials.

#### **CONTACT:**

Dana Dornsife, CEO and Founder Lazarex Cancer Foundation (925) 820-4517 <u>dana@lazarex.org</u> www.lazarex.org