SDOH Impact on Equity and Diversity in Clinical Trials
January 12, 2021
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 + | CulturlInteI

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  Panel Discussion
2:05 -2:15 pm  Closing Thoughts
Our Work

**EDUCATION**
- Expert Roundtables
- Education Programs
- Webinars, Workshops
- Networking Receptions
- Surveys Reports

**ADVOCACY**
- Recommendations
- Privacy Policy
- Comment Letters
- Policy Steering Committee (PSC)
- Capital Hill Briefings
- HHS, FTC, OCR, Relationships
- Hill Meetings

**THOUGHT LEADERSHIP**
- Expert Roundtables
- Advisory Boards, Workgroups
- Grants/ Partnerships
- HHS, FTC, OCR, Relationships
- Surveys, Reports
- Expert Faculty

www.ehidc.org
eHealth Initiative Members

- Accenture
- American College of Cardiology
- American College of Physicians
- American Academy of Family Physicians
- American Hospital Association
- Allscripts
- Amwell
- Availity
- Best Buy Health
- BlueCross BlueShield Association
- Booz Allen Hamilton
- Bristol-Myers Squibb
- CAQH
- Change Healthcare
- Epstein Becker Green
- Commonwell Health Alliance
- Conversa
- CORHIO
- CRISP
- CVS Health
- EHNAC
- Elsevier
- Fitbit
- Google Cloud
- Gunderson Health System
- Accelerate Discovery
- Health Catalyst
- healthcurrent
- Healthx
- Hogan Lovells
- Humana
- Inovalon
- InterSystems
- Johnson & Johnson
- LexisNexis Risk Solutions
- LifeWIRE
- Lockheed Martin
- Manatt
- Maverick Health Policy
- Marshfield Clinic
- Mayo Clinic
- MedAllies
- MGMA
- Milken Institute School of Public Health
- National Alliance of Healthcare Purchaser Coalitions
- Nebraska Health Information Initiative
- Nextgen Healthcare
- Northwell Health
- OhioHealth
- Orion Health
- Point of Care Partners
- Providence
- St. Joseph Health
- SHIEC
- SHINE
- Sonora Quest Laboratories
- Strategic Interests
- Surescripts
- Tapestry
- The Commons Project
- UChicago Medicine
- UnitedHealthcare
- Updoc
- VALIDIC
- Verato
- Welldoc
- Wellmark
- Zynosis
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

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

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
2020 Publications

- **Building a Modern Health Care System: Recommendations from the COVID-19 Federal Policy Work Group**
- **Supporting American Indian & Alaskan Native Communities Combating COVID-19**
- **Understanding Data Gaps, Needs and Strategies 2020**
- **Proposed Consumer Privacy Framework for Health Data**
  - Draft for Public Feedback
  - August 28, 2020
- **Executive Summary of Final Rule**
- **Examples from the Field 2020**

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Upcoming Forums & Webinars

January 20th: New Strategies for Patient Engagement: Lessons Learned During the Pandemic

January 26-28th: eHI Annual Member Meeting

February 3rd: 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

- All participants are muted

- 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

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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 Pandemic and clinical trials have highlighted longstanding healthcare disparities and amplified the importance of participation of impacted communities in research and development of healthcare solutions.
Participant barriers to clinical trial diversity

- 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

Mistrust
Fear
Lack of comfort with process
Logistical constraints such as time, out-of-pocket expenses, transportation, etc
Lack of Awareness and/or information about clinical trials
Social determinants of health

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

<table>
<thead>
<tr>
<th>Economic stability (income, employment, debt, expenses, etc.)</th>
<th>Racial and ethnic minorities experience higher economic instability. Implicit costs (transportation, childcare, parking, loss of income from missing work) can lead to low participation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Education (literacy, linguistic fluency, vocational training, and higher education)</td>
<td>Individuals with low levels of education may find information about research trials and informed consent to be complex and difficult to comprehend.</td>
</tr>
<tr>
<td>Neighborhood and built environment (transportation, safe/modern housing, sidewalks, etc.)</td>
<td>An individual’s environment (transportation, access to health care and research sites) may limit ability to participate in research studies.</td>
</tr>
<tr>
<td>Health and health care (availability of health coverage/specialist HCP, QOC, cultural competency)</td>
<td>Access to care, quality of care, and insurance coverage have been given as reasons for some patients’ refusal to participate in research studies.</td>
</tr>
<tr>
<td>Social and community context (social integration, community engagement, trust, and social support)</td>
<td>Discrimination and exploitation of minority communities has led to mistrust and suspicion of healthcare systems and research.</td>
</tr>
</tbody>
</table>

Recognizing and addressing SDOH to increase clinical trial diversity

- Economic Stability
- Social/ Cultural context
- Health Literate Communications, Education & Training
- Safe and affordable transportation options
- Access and availability of health care
- Discrimination
- Digital Divide
- Neighborhood and Built Environment
- Education
- Community engagement, collaborations and partnerships
- Leverage RWD to improve site selection, participant & workforce diversity
- Policy initiatives to address disparities, reduce out-of-pocket costs
- Increase digital, computer, internet, virtual access and literacy
- Increase screening and collection of SDOH data
Patient and community engagement support diverse participation

- Forming Relationships
- Training and Support
- Shared Goals
- Sustained partnerships
- 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.*
DECODING CLINICAL TRIAL ROI

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www.cien.plus | Proudly women-owned and minority owned
4KEY

TRENDS TO
CONSIDER
SIZE & GROWTH: Fast approaching majority-minority nation by 2040

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

Source: pewresearch.org and U.S. Census

U.S. POPULATION

White  Black  Hispanic  Asian  All other
DIVERSITY ACROSS TOP 4 MOST POPULOUS STATES

2040 IS TODAY
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
High growth diverse segments are disproportionately affected by chronic diseases.
#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

Centers of Medicare & Medicaid Services (CMS) wants to have 100 percent of providers taking on some downside financial risk by 2025.

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.

Source: According to healthcare leaders in a recent survey conducted by HealthCare Executive Group (HCEG) and Change Healthcare.
#4 Lack of clinical trial diversity compromises the promise of personalized medicine

But estimates place the rate of inclusion in research studies between 2% - 16%

Source: As precision medicine grows, so does the importance of clinical trial diversity
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.

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.
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.”
<table>
<thead>
<tr>
<th>Overall N=372K</th>
<th>Black Americans N=30K</th>
<th>Hispanics N=19K</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Lack of awareness 38%</td>
<td>HCP concerns 27% [3X \text{vs. overall}]</td>
<td>HCP concerns 27%</td>
</tr>
<tr>
<td>2. Fear &amp; anxiety 31%</td>
<td>Lack of awareness 24%</td>
<td>Application process 23% [3X \text{vs. overall}]</td>
</tr>
<tr>
<td>3. HCP concerns 11%</td>
<td>Fear &amp; anxiety 21%</td>
<td>Costs 22% [2X \text{vs. overall}]</td>
</tr>
<tr>
<td>4. Costs 10%</td>
<td>Application process 17% [2X \text{vs. overall}]</td>
<td>Lack of awareness 19%</td>
</tr>
<tr>
<td>5. Application process 10%</td>
<td>Costs 11%</td>
<td>Fear &amp; anxiety 9%</td>
</tr>
</tbody>
</table>

**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
2. The difficulty of the application process
3. The anticipated costs

Beyond lack of awareness and fear/anxiety, top 2 barriers for overall.
The ability to be aware of, understand and apply cultural competence and inclusive data into everyday business.
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.

clinicaltrialdiversity.com
Thank You!

Lili Gil Valletta
(908) 616-4177
liliana@cien.plus
Diversity in Clinical Trials #DCT

The Need for greater DIVERSITY in Clinical Trials
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
Understanding the Global Nature of Diversity
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.

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.
- Hispanics represent 16% of the US population but only ~3% participate in clinical trials.
- Asian Americans represent 6% of the US population but only ~3% participate in clinical trials.

Adapted from FDA Drug Trials Snapshots Summary Report 2015 - 2019
# 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
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 & Caregiver-facing Materials**
Create focused clinical trial materials targeted to specific populations

**Site Selection**
Develop strategy aligned with the epidemiology of disease or condition being studies
Diversity in Clinical Trials #DCT

Case Study
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\(^1\)

**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

\(^1\) Cancer Facts & Figures 2020  
\(^2\) Annals of Oncology, Volume 27, Issue 12, December 2016
Thank you
TRANSFORMING BENCH TO BEDSIDE
Adopting clinical trial navigation, community engagement, and a financial reimbursement model to remove barriers, increase overall enrollment, and achieve equitable access and inclusion among racial/ethnic minorities in therapeutic cancer clinical trials

MISSION
Improving patient access to cancer clinical trials
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.
Lazarex Programs

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

Structured
- Institutional Focus
- Action Specific
- Health Professional Referral during TCT Consent
- Travel Expense Reimbursement
- Community O & E
- 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

CANCER HUB WELLNESS
Increased Enrollment & Diversity – Equitable Access!

Navigation & Reimbursement Process

Identify Clinical Trials → Apply for Reimbursement → Determine Eligibility Level

Generate Agreement → Reimburse Monthly

50% 75% 100%
The Community IMPACT Process

Identify Location
Create Team
Conduct Assessment

Form Action Plan
Engage with Community
Measure Results

Addressing Health Disparities and Improving Outcomes!
# EHTNICITY DATA

<table>
<thead>
<tr>
<th>Race / Ethnicity</th>
<th>CARE January 2015 - August 2020</th>
<th>CARE January 2018 to August 2020</th>
<th>IMPACT January 2018 to August 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of Patients</td>
<td>Percentage</td>
<td>Number of Patients</td>
</tr>
<tr>
<td>American/Alaskan Indian</td>
<td>0</td>
<td>0%</td>
<td>0</td>
</tr>
<tr>
<td>Asian/Pacific Islander</td>
<td>58</td>
<td>4%</td>
<td>18</td>
</tr>
<tr>
<td>Black/African American</td>
<td>130</td>
<td>8%</td>
<td>65</td>
</tr>
<tr>
<td>Latino/Hispanic</td>
<td>190</td>
<td>12%</td>
<td>53</td>
</tr>
<tr>
<td>Multi-Ethnic</td>
<td>12</td>
<td>1%</td>
<td>8</td>
</tr>
<tr>
<td>White</td>
<td>1171</td>
<td>75%</td>
<td>491</td>
</tr>
<tr>
<td><strong>Sub-Total</strong></td>
<td><strong>1561</strong></td>
<td><strong>100%</strong></td>
<td><strong>635</strong></td>
</tr>
<tr>
<td>Unspecified</td>
<td>53</td>
<td></td>
<td>20</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1614</strong></td>
<td></td>
<td><strong>655</strong></td>
</tr>
</tbody>
</table>

- **25% Minority Participation** for CARE January 2015 - August 2020
- **23% Minority Participation** for CARE January 2018 to August 2020
- **63% Minority Participation** for IMPACT January 2018 to August 2020
# Results

## Household Income Data

<table>
<thead>
<tr>
<th>Income Range</th>
<th>CARE January 2015 - August 2020</th>
<th>IMPACT January 2018 to August 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of Patients</td>
<td>Percentage</td>
</tr>
<tr>
<td>Less than $15,000</td>
<td>287</td>
<td>18%</td>
</tr>
<tr>
<td>$15,000 - $24,999</td>
<td>207</td>
<td>13%</td>
</tr>
<tr>
<td>$25,000 - $34,999</td>
<td>191</td>
<td>12%</td>
</tr>
<tr>
<td>$35,000 - $49,999</td>
<td>259</td>
<td>16%</td>
</tr>
<tr>
<td>$50,000 - $74,999</td>
<td>308</td>
<td>19%</td>
</tr>
<tr>
<td>$75,000 - $99,999</td>
<td>215</td>
<td>13%</td>
</tr>
<tr>
<td>More than $100,000</td>
<td>147</td>
<td>9%</td>
</tr>
<tr>
<td>Total</td>
<td>1614</td>
<td>100%</td>
</tr>
</tbody>
</table>

31% income less than 25K  
25% income less than 25K  
52% income less than 25K
Care Reimbursements

IMPACT Reimbursements

- Flights
- Lodging
- Ground
- Gas Tolls Parking

Results
Racial / Ethnic Diversity Dependent upon Local Catchment Areas

- San Francisco
- Los Angeles
- Philadelphia

Catchment Area Variation

- Asian
- Black / African American
- Latino / Hispanic
- White
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:
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