Center for Healthcare Innovation

AGREEDementia

From Researcher to Patient - Making Clinical Trials More Diverse

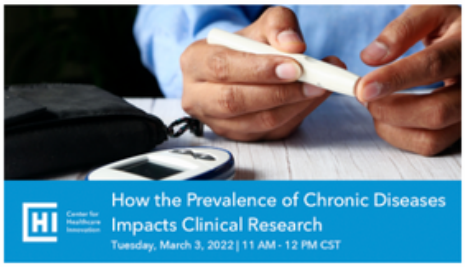
SERIES SUMMARY

A year-long virtual series providing an in-depth exploration and review of clinical trial diversity in the U.S.

From Researcher to Patient: Making Clinical Trials More Diverse

OVERALL PROJECT GOAL

This 10-part virtual program series provides an in-depth exploration and review of diversity in clinical trials in the U.S. According to the FDA, African Americans and Hispanics comprise only 8% and 11% of clinical trial participants in the U.S. while comprising 13% and 19% of the total U.S. population. CHI's educational series will convene many of the country's leading clinical trial and diversity experts, physicians, scholars, researchers, authors, and key opinion leaders to explore the factors that have led to the historical and current underrepresentation of BIPOC patients in U.S. clinical trials. This educational series also provides best practices, new clinical and research insights, and novel trends in building a more diverse and inclusive clinical trial and research ecosystem in the U.S.



MICROAGGRESSIONS AND IMPLICIT BIASES IN HEALTHCARE

TUESDAY, JANUARY 4, 2022 | 11:00 AM - 12:00 PM CST

MODERATOR
Dr. Neelum Aggarwal, MD

PANELISTS
Ms. Mori Johnson, MA

Dr. Carl Lambert, Jr., MD, FAAFP

WEBINAR DESCRIPTION

This educational program explores racial microaggressions and biases in the healthcare industry, including how they impact patient health outcomes employees of healthcare organizations. Microaggressions and implicit biases in the clinical care setting have a detrimental impact on patients' evaluation of needed services, health outcomes, patients' perception of the healthcare system, and overall quality of care. A University of Virginia study in 2016 found that 73% of White medical students held "at least one false belief about the biological differences between races." In another example, the 2015 National Healthcare Quality and Disparities Report found that Black, Latin, American Indian, and Alaskan Native individuals receive worse care than White individuals for approximately 40% of quality measures. Moreover, microaggressions and implicit biases in the workplace impact employee productivity, organizational development, and external perception, among other negative outcomes. A 2019 Deloitte study found that "whether based on gender, age, race, ethnicity, sexuality, disability or military status, more than 60% of respondents reported a presence of bias in their workplace." Additionally, 70% of Black physicians and 69% of Asian physicians have experienced patient bias. For patients and providers alike, microaggressions and biases on the basis of race remain present and lead to a significantly lower quality of care. This educational program brings together a distinguished group of industry experts to discuss strategies for patients, providers, teams, and organizations to address, reduce, and ultimately eliminate microaggressions.

KEY TAKEAWAYS

1. Lead by example
    a. Commit to a lifelong journey of learning about other cultures, particularly of those most marginalized, and model your behavior based on those learnings.
2. Incorporate cultural humility into your organization
    a. Provide workplace trainings, town halls and forums to share experiences, and review existing policies through an equity lens.

UNDERSTANDING HEALTH LITERACY FOR CLINICAL RESEARCH ENROLLMENT

THURSDAY, FEBRUARY 3, 2022 | 11:00 AM - 12:00 PM CST

MODERATOR
Dr. Neelum Aggarwal, MD

PANELISTS
Dr. Melva Covington, PhD, MPH, MBA
Dr. Sarah Hartz, MD, PhD
Dr. Jessica Mozersky, PhD, MBE

WEBINAR DESCRIPTION

This program explores the intersection of health literacy and recruiting patients of color to make clinical trials more diverse, equitable, and accessible. The U.S. Department of Health and Human Services defines health literacy as "the degree to which individuals can find, understand, and use information and services to inform health-related decisions and actions for themselves and others." Data indicates that only 36% of Americans have basic or below basic health literacy skills. Lower health literacy is also more common in older adults, communities of color, and medically underserved Americans. Additionally, limited health literacy costs the healthcare system money and results in higher than necessary morbidity and mortality. The CDC estimates that improving health literacy could prevent nearly 1 million hospital visits and save over $25 billion annually. Moreover, health literacy can impact clinical trial patient recruitment. According to Clinedge, over 75% of all trials fall short of patient enrollment goals, and health literacy is a significant cause. Furthermore, patients of color and other diverse groups are underrepresented in clinical research. Overall, low health literacy and lack of accessibility in clinical trials leads to unrepresentative trials and ultimately worse health outcomes for these underrepresented communities. This program brings together experts to discuss effective strategies for properly communicating clinical trials to under-represented groups to make trials more diverse and representative of the U.S. population.

KEY TAKEAWAYS

1. Understand how and where patients receive information
    a. To improve health literacy, address the rise of misinformation, and build trust, health professionals must engage with patients through familiar avenues of information.
2. Leverage new technology to reach new communities
    a. Novel technology, such as telemedicine, enables organizations to build new outreach models and reach underrepresented communities.
3. Uphold cultural humility
    a. Operating from a mindset of cultural humility builds trust and enables care that is centered in the patient and their framework of understanding.

HOW THE PREVALENCE OF CHRONIC DISEASES IMPACTS CLINICAL RESEARCH

TUESDAY, MARCH 3, 2022 | 11 AM - 12 PM CST

MODERATOR
Dr. Neelum Aggarwal, MD

PANELISTS
Dr. Monica Parker, MD

Dr. Jeff Sherman, MD, FACP

WEBINAR DESCRIPTION

This education program focuses on chronic medical conditions in underrepresented groups and how these conditions impact clinical trial participation. Specifically focusing on kidney diseases, the discussion will center around eligibility criteria, safety, and dialogue with patients from underrepresented communities. One study in the "Current Problems in Cardiology" journal found that a “lack of diversity in clinical trials is a moral, scientific, and medical issue. When trial participants are homogenous (e.g., primarily one gender, race/ethnicity, or age group), findings may be skewed and result in a body of clinical knowledge that is not generalizable”. New NIH data shows that “35% of African Americans suffer from kidney failure and Hispanics have experienced a 70% increase in kidney failure cases since 2000”. Furthermore, a study in the American Journal of Nephrology showed that African Americans are “10 times more likely to develop kidney failure related to hypertension, and 3 times more likely to progress to kidney failure than Caucasians”. Additionally, in 3,000 chronic kidney disease-related clinical trials, only 34 were directed toward African Americans. With African Americans comprising 13.2% of the U.S. population and having an elevated risk, this number is exceptionally low. Chronic disease is disproportionately prevalent in marginalized communities and ultimately leads to lower clinical trial participation, which in turn leads to less representative data and worse health outcomes for these communities. This educational program brings together industry experts to discuss the impact of chronic conditions on clinical trial enrollment in underrepresented groups and solutions to address barriers in trial participation related to chronic diseases through patient communication, revised eligibility criteria, and community engagement.

KEY TAKEAWAYS

1. Analyze and revise trial eligibility to improve recruitment
    a. Clinical researchers must critically analyze eligibility criteria to account for comorbidities and seek out communities that are being unintentionally left out
2. Create adequate time early in recruitment for potential challenges
    a. Clinical researchers must leave extra time when recruiting from different or underrepresented communities to address potential challenges from working with a new community.

3. Develop culturally competent approaches for communicating trial details
    a. Using culturally appropriate language and communication methods, particularly with the risks and benefits of the trial, will aid patient understanding and build greater trust in the trial.

THE INTERSECTION OF GENETICS & CANCER IN CLINICAL TRIALS

THURSDAY, APRIL 7, 2022 | 11 AM - 12 PM CST

MODERATOR
Dr. Neelum Aggarwal, MD

PANELISTS
Ms. Ricki Fairley, MBA

WEBINAR DESCRIPTION

This program focuses on the intersections of genetics, Black Breast Cancer, and clinical trials. Black women are 41% more likely to die of breast cancer than White women, with Black breast cancer patients experiencing the lowest 5-year survival rate of any race or ethnicity. Overall 5-year relative survival rates are 81% for Black women compared to 91% for White women. Black women under 35 get breast cancer at twice the rate and die at three times the rate. A 2021 study published in Cancer Medicine found that Black women have a nearly three-fold increased risk of Triple-Negative Breast Cancer - an aggressive subtype of breast cancer. Despite these disturbing statistics, Black women are largely excluded from trials that study breast cancer drugs and treatments, which means that these fundamental safety and efficacy concerns aren't being answered for Black women's bodies. Moreover, with low participation rates in clinical trials, Black women miss access to newly emerging and often life-extending treatments not otherwise available. As documented by JCO Precision Oncology, Memorial Sloan Kettering Cancer Center, and many others, Black women experience many cancer drug side effects differently. Trial data, the resulting treatment protocols, and product development don't account for the many factors of Black Breast Cancer. We will not be able to change the devastating Black Breast Cancer mortality numbers unless we understand the physiology of Black women. We cannot do that until we have more Black women participating in clinical research. Featuring the expertise of Ms. Ricki Fairley, a breast cancer survivor and clinical trial expert, the webinar will discuss how to address common pitfalls that result in the underrepresentation of Black women in cancer clinical trials.

KEY TAKEAWAYS

1. Be transparent with the facts about the clinical trial
    a. Being upfront and honest about the details of the trial, including benefits, risks, and existing data, will build trust and improve participation
2. Prioritize patient experience in study design
    a. Being cognizant of patient experience, such as where trials are conducted, can increase convenience, accessibility, and ultimately improve participation.

HEALTH EQUITY CONCERNS OF DECENTRALIZED CLINICAL TRIALS

THURSDAY, JUNE 2, 2022 | 11 AM - 12 PM CST

MODERATOR
Dr. Neelum Aggarwal, MD

PANELISTS
Dr. Fan Gao, PhD, MS

Dr. Scott Treiber, PhD, MBA

WEBINAR DESCRIPTION

The COVID-19 pandemic has accelerated a paradigm shift in the execution of clinical trials from site-based to decentralized trials, emphasizing increasing convenience and access to patients. Regulators' sentiment is in lockstep with the industry, issuing guidance for implementing telemedicine services, remote monitoring, and home health visits. As broader adoption of decentralized trial activities continues, addressing health equity concerns around the "digital divide" or unequal access to internet technologies between low and high socioeconomic status (SES) populations must also be broad. Patient recruitment strategies must mitigate the barriers experienced by low SES populations who more commonly lack the prerequisite tools, such as broadband internet, to benefit from decentralized services such as electronic consent and video conferencing. According to Health and Human Services, 45% of people in poverty lacked broadband internet, with 26% having no internet access in 2019. This digital disparity becomes more pronounced based on age, race and ethnicity, and geography. Low SES minority groups were less likely to have broadband internet, such as African Americans with 57% and Latinos with 52%, compared to their White counterparts with 44%. The digital gap is just as stark in the elderly groups, with 40% of those living in poverty lacking internet access. Finally, low SES households living in non-metropolitan areas were 7% less likely to have internet access than their metropolitan dwelling counterparts. Low SES and minority populations have long been underrepresented in clinical trials. As such, decentralized or hybrid clinical trial designs could benefit from incorporating health equity best practices into enrollment and retention plans. By convening many of the country's leading clinical trial and diversity experts, physicians, scholars, authors, and key opinion leaders, this program will explore health equity concerns of decentralized clinical trials in the U.S. This program will also provide best practices, new insights, and novel trends in building a more diverse and inclusive clinical trial ecosystem in the U.S. to explore health equity concerns in decentralized clinical trials.

KEY TAKEAWAYS

1. Be open to designing your study differently
    a. By investigating novel methods and technologies, researchers can find creative solutions to previous challenges in representation.
2. Approach new technology with an eager but critical mindset
    a. Although technology can provide benefits in reaching new audiences, researchers should remain careful of other potential barriers, such as low digital literacy.
3. Avoid overemphasizing "positive" outcomes
    a. Despite the existing incentives towards "positive" results in research, it is also helpful to share results of what didn't work, particularly with trying new technology methods.

INCREASING DIVERSITY AMONG PRINCIPAL INVESTIGATORS & THE CLINICAL TRIAL COMMUNITY

THURSDAY, SEPTEMBER 1, 2022 | 11 AM - 12 PM CST

MODERATOR
Dr. Neelum Aggarwal, MD

PANELISTS
Dr. Carl Hill, PhD, MPH

Dr. Monica Parker, MD

WEBINAR DESCRIPTION

This educational program will explore the relationship between communities of color, who are often underrepresented in clinical trials, and diverse teams of principal investigators. The discussion will focus on how building diverse teams of healthcare professionals and clinical trialists may result in better clinical trial patient recruitment and overall trial success. A 2020 study indicated that only 23% of African Americans and 26% of Latin Americans have a physician that shares the same race or ethnicity, while for White Americans, that number is 82%. Moreover, research often shows that minority patients prefer to be treated by minority doctors, and racial concordance between patients and providers may lead to better health outcomes. For example, in an analysis of over 100,000 patient surveys from 2014 to 2017, a team of Penn Medicine researchers found that patients were more likely to give the maximum patient rating score when they shared the same racial or ethnic background as their physician. Lack of clinical workforce diversity has a clear impact on efficacy of and participation in clinical trials. This educational program convenes a group of clinical trial experts to discuss how increasing diversity among providers, principal investigators, and other clinical trial professionals may improve clinical trial recruitment among communities of color. This program is in partnership with the Black Healthcare & Medical Association.

KEY TAKEAWAYS

1. Increase clinical research exposure in higher education
    a. To increase clinical research workforce diversity, educational institutions and researchers must intentionally partner and demonstrate clinical research as a viable career path, particularly for undergraduates and master's students.
2. Foster partnerships between clinical work and researchers
    a. Physicians and providers must find where research is happening and become a partner to better expand opportunities for their patients and improve representation.

ENGAGING HISTORICALLY UNDERREPRESENTED ASIAN COMMUNITIES IN CLINICAL TRIALS

THURSDAY, OCTOBER 20, 2022 | 11 AM - 12 PM CST

MODERATOR
Dr. Neelum Aggarwal, MD

PANELISTS
Dr. Navneet Kathuria, MD, MPH, MBA

Dr. Hina Mehta, PhD, MBA

WEBINAR DESCRIPTION

This program explores the root causes of the underrepresentation of Asian Americans in U.S. clinical trials. According to the FDA's 2015-2019 Drug Trials Snapshots Summary Report, Asian comprised just 2% of U.S. clinical trial participants while comprising 6% of the overall U.S. population. Additionally, the latest census bureau data indicated that 20 million Americans identified as "Asian," and another 4 million checked boxes as "Asian" combined with another race group, for a total of 7.2 percent of the population. The results make the Asian population the fastest-growing racial group in the United States at 35.5%. Many of the nation's leading health equity advocates and clinical trial leaders are concerned with the underrepresentation of specific Asian subgroups, overall demographic trends, and a growing Asian population in the United States. These concerns stem from various factors, including social determinants of health, P.I. and clinical trialist demographics, and cultural and linguistic pitfalls. This program convenes a group of clinical trial experts, providers, and DEI executives to discuss best practices and recommendations for making clinical trials more inclusive for Asian Americans.

KEY TAKEAWAYS

1. Encourage community participation
    a. Awareness must be raised from within underrepresented communities to encourage participation in clinical trials.
2. Engage with community organizers
    a. Engaging with organizers in your community strengthens the conversation and leads to unique insights toward addressing underrepresentation in clinical trials.
3. View clinical research as a true partnership with the community
    a. By sharing resources and emphasizing cultural humility in your approach to research, underrepresentation in clinical trials can better be addressed with support from the communities themselves.

ENGAGING HISTORICALLY UNDERREPRESENTED HISPANIC COMMUNITIES IN CLINICAL TRIALS

THURSDAY, OCTOBER 27, 2022 | 11 AM - 12 PM CST

MODERATOR
Dr. Neelum Aggarwal, MD

PANELISTS
Dr. Paula Espinal, MD, MPH

Dr. Antonio Tito, PhD

WEBINAR DESCRIPTION

This program explores the root causes that result in the underrepresentation of Latin Americans in U.S. clinical trials. According to the FDA, Latin Americans comprised only 11% of the total clinical population for drugs approved in 2020, while Latin Americans comprise almost 19% of the total U.S. population. Furthermore, the number of Latin Americans in the U.S. is rapidly growing, and Latin Americans currently account for over half of the country's population growth. This discordance results from various factors, including social determinants of health, P.I. and clinical trialist demographics, and cultural and linguistic pitfalls. Understanding and addressing the specific needs of these communities will enable better representation and ultimately address health disparities in this population. This program convenes a group of clinical trial experts, providers, and DEI executives to discuss best practices and recommendations for making clinical trials more inclusive for Latin Americans.

KEY TAKEAWAYS

1. Call for action
    a. Talk and ask questions to researchers, physicians, and other professionals involved in clinical trials to drive for better representation.
2. Immerse yourself in the community
    a. Before cementing the details of the clinical trial, get to know the community and understand what their perspectives are to better tailor your research and improve community participation.

ENGAGING HISTORICALLY UNDERREPRESENTED MEMBERS OF THE LGBTQ COMMUNITY IN CLINICAL TRIALS

THURSDAY, NOVEMBER 17, 2022 | 11 AM - 12 PM CST

MODERATOR
Dr. Neelum Aggarwal, MD

PANELISTS
Mr. Donald Bell
Mr. Christopher Cannon, MPH
Mr. Darryl Mitteldorf, LCSW

WEBINAR DESCRIPTION

This educational program will explore strategies to engage members of LGBTQ communities for participation in clinical trials. The discussion will focus on best practices for patient-centered engagement that can result in better clinical trial patient recruitment and retention. According to the Human Rights Campaign Foundation, approximately 20 million adults, or 8% of the U.S. population, identified as lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ) on the 2020 U.S. Census Bureau's Household Pulse Survey. The LGBTQ community comprises an increasingly diverse group with unique health needs that remain underserved and understudied, resulting in health disparities. In the oncology space, LGBTQ individuals have lower rates of cancer screening, higher rates of anal and cervical cancer, and greater breast cancer mortality. Continued underrepresentation in clinical trials limits the generation of clinical data that is essential for developing effective treatments for LGBTQ patients. An analysis conducted by the American Association for Cancer Research revealed that out of 348 sexual and gender minority studies funded by the NIH in 2018, less than 8% focused on cancer. Furthermore, quantifying LGBTQ representation in cancer drug trials is impeded by inconsistent data collection practices for sexual orientation and gender identity demographics. In a survey of 53 NCI Community Oncology Research Program practice groups, only 24% routinely collected sexual orientation data. Common barriers unique to LGBTQ communities include mistrust and lack of understanding of the clinical trials process, fears of exploitation, confidentiality, and study design concerns. Strategies for addressing these barriers must start with engaging community members and advocacy groups to provide input on research design, cultural competency training for research staff, and research education. This program convenes a group of clinical trial experts, providers, and DEI executives to discuss best practices and recommendations for making clinical trials more inclusive for LGBTQ communities.

KEY TAKEAWAYS

1. Examine biases and prejudices
    a. Make a conscious effort to see beyond preconceptions and stereotypes to see the community for what it truly is rather than how it may commonly be portrayed.
2. Critically analyze your research goal
    a. Understand exactly and specifically what the goal of your study is when designing it. If the goal is to study everyone, then allow the true aim of your research to drive study design and guide you to engage with these communities.
3. Actions must match words
    a. Ensure that the push for diversity and inclusion extends to action and does not remain only as a virtuous mission statement.

ENGAGING HISTORICALLY UNDERREPRESENTED MEMBERS OF THE AFRICAN AMERICAN/BLACK COMMUNITIES IN CLINICAL TRIALS

WEDNESDAY, DECEMBER 7, 2022 | 11 AM - 12 PM CST

MODERATOR
Dr. Neelum Aggarwal, MD

PANELISTS
Ms. Nicole Bettè
Dr. Doris Molina-Henry, PhD
Ms. Leonore Okwara, MPH
Ms. Gelise Thomas, JD, MS
Ms. Rochonda Woodard

WEBINAR DESCRIPTION

Developing strategies to engage clinical trial participation in underrepresented groups will require a thorough understanding of past challenges, current attitudes, and future implications. Almost 50 years after the unethical research practices in the Tuskegee Syphilis study caused public outrage, remnants of mistrust among African American/Black communities continue to impact confidence in clinical trials. Despite decades of reforms to establish basic research standards and protect the rights of trial participants, African American/Black communities remain underrepresented in clinical trials. In a 2020 FDA report on clinical trials resulting in 53 novel drug approvals, African Americans represented only 8% of U.S. clinical trial participants despite comprising 13% of the U.S. population. Across therapeutic areas, the gap between the disease population and trial representation widens. For example, in multiple myeloma (MM) oncology trials, a disease in which Black Americans account for approximately 20% of annual cases, the median percentage of Black Americans enrolled across 21 pivotal trials was just 4.5%. Strategies for proportional clinical trial representation must address cultural barriers to enrollment and improve upon outdated recruitment and retention practices. Increasing African American/Black participation in clinical trials ensures that treatments are adequately tested in populations to whom it will be marketed. Increased diversity in clinical trial populations can also yield racial and ethnic differences in disease progression and drug response across demographic groups. By convening many of the country's leading clinical trial and diversity experts, physicians, scholars, authors, and key opinion leaders, this program will provide best practices, new insights, and novel trends in building a more diverse and inclusive clinical trial ecosystem in the U.S.

KEY TAKEAWAYS

1. Utilize DEI legislation on research to inform your practices
    a. Although many bills are not being passed, they still contain useful information regarding research and incorporating DEI efforts.
2. Acknowledge the humanity in all patients
    a. Although statistics is a useful tool, patients will always be more than a number, and remaining cognizant of this idea is necessary for nurturing and cultivating a relationship.
3. Learn your community
    a. Listen to people in the community you wish to study, and utilize these insights and relationships to inform your study design.

OVERALL INSIGHTS

This educational series explored many different facets of diversity, equity, and inclusion in clinical research, yet these key themes and insights consistently emerged.

Increase clinical research workforce diversity

A more representative workforce will increase engagement and participation among underrepresented communities. As such, we must invest in pipelines to clinical research, both early on and in higher education.

Engage with the community early

Enough time must be allocated early on to build and sustain relationships with the community so that their input is directly included in the study design process instead of as an afterthought.

Partner with community leaders and organizations

Within engaging with the community, finding and forming true partnerships with existing leaders and organizations will enable better understanding of the community and overall participation.

Recognize the true diversity within communities

Although grouped under general labels, such as "Hispanic" or "Asian," understand that there is often a deeper level of granularity and that these communities are not monolithic. This further extends to intersectional identities.

Healthcare providers and clinical researchers must form partnerships

Clinical researchers and providers must seek one another out to increase awareness of study opportunities and improve representation.

Be willing to learn and adapt

Whether it's working with a new community or utilizing novel technology, researchers must embrace changing aspects of the clinical trial, such as study design, eligibility criteria, and outreach methods, to generate true, useful, and representative data.

Consider novel technologies with a critical mindset

New technologies, such as telemedicine, represent opportunities to reach new populations. However, researchers must remain cautious and critical to address other challenges, such as the digital divide.

Be a voice for advocacy in spaces you occupy

Regardless of your role in clinical research, awareness of the necessity of diversity and inclusion in clinical research must be raised.

Our vision is to be the leading global platform for meaningful change in health equity.

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