Discussions on Diversity

The recent events of the racial justice movement and the disproportionate impact of the COVID-19 pandemic, particularly within Black, Latinx, Asian and Indigenous communities, highlight the need for more equitable access to healthcare and clinical trials. Listening and learning from patients and physicians about critical barriers and ways to overcome them are therefore important steps to successfully achieving meaningful change.

Through this report and the series of reports and white papers to follow, we will share feedback from both our quantitative and qualitative research sources to support greater understanding and highlight areas for action.

Diversity Research Participants Voices

Gain in-depth, expert insight from a range of seasoned professional with extensive knowledge about patient advocacy, life sciences, and how they impact diversity, equity, and inclusion.

Yasmeem Watson

"There is mistrust among diverse, underserved communities pertaining to the medical sector. This report identifies some of the obstacles...."

Read more >

Malini Raj

"Our society is not homogenous; hence, a one-size-fits-all approach is not appropriate, particularly when it comes to such an important and sensitive issue as health...."

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Minnie Baylor-Henry

"As we face the many complexities of a public health crisis brought about by a global pandemic, Black and Brown people, along with other disaffected people globally...."

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Dr. Valerie Stone

"Black, Indigenous and People of Color (BIPOC) are disproportionately affected by every major disease. This is true of diabetes mellitus, hypertension...."

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What's In The Report

A brief overview of the insights we've gained and the methods leveraged to produce this report.

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Key Findings

Select a chapter for more info

- Building Relationships & Trust
- Research Awareness and Understanding
- COVID-19 Perceptions
- Increasing Research Involvement
- Practical Barriers
- Decentralized Clinical Trials (DCTs)
- Institutional and structural racism
- Trial Feasibility
- Disease Perceptions

SEE FULL CONTENT STREAM

Yasmeem Watson

Yasmeem Watson is a research, patient and consumer advocate, as well as a Stage III colon cancer survivor. She is a member of Fight Colorectal Cancer's (FCRC) Research Advocacy Training and Support (RATS) Program and has dedicated herself to impactful research advocacy initiatives, including but not limited to serving as a consumer advocate on the Department of Defense's Peer Review Cancer Research Program, the Alliance for Clinical Trials in Oncology, the Patient-Centered Outcomes Research Initiative (PCORI) and the American Association for Cancer Research Scientist↔Survivor Program.

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There is mistrust among diverse, underserved communities pertaining to the medical sector. This report identifies some of the obstacles and factors in needed solutions. The patient's voice is of most importance if the goal is to diversify clinical trials. There are many components of a patient's journey, yet not feeling acknowledged may be the most heartbreaking. The feeling that your skin color or language is not a barrier to receiving adequate care is priceless.

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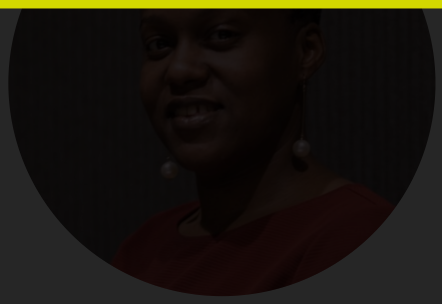
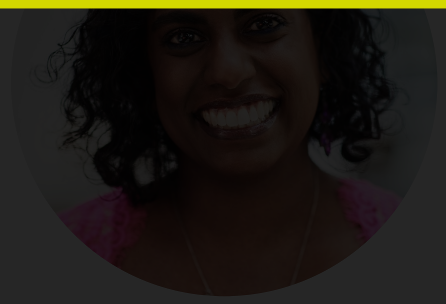
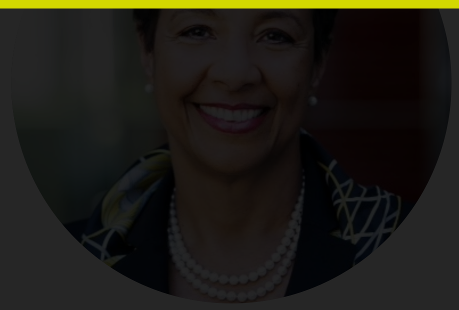


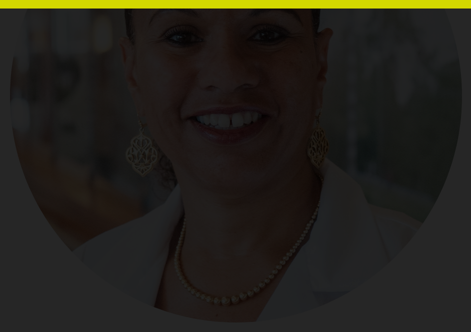
Yasmeem Watson



Malini Raj



Minnie Baylor-Henry



Dr. Valerie Stone

SEE FULL CONTENT STREAM

Malini Raj

Malini Raj is a patient advocate, Non-Executive Director of the Australian Pituitary Foundation and member of the World Alliance of Pituitary Organizations. Malini is a strong patient advocate for Cushing's disease, since she is a patient herself, diagnosed in 2013 after a 20-year journey to diagnosis.

Our society is not homogenous, hence a one size fits all approach is not appropriate. This is particularly true when it comes to such important and sensitive issues as health and the design of clinical trials and research approaches in order to optimize outcomes for all stakeholders.

Society as we know it is extremely ethnically diverse and multicultural. Each of these minority groups have specific needs, views, opinions and cultural nuances which shape the way they interact, react or engage in society and how they are impacted. These unique characteristics need to be considered, acknowledged and incorporated to ensure these groups are adequately represented in clinical research. As a patient from an ethnic minority group, I commend Parexel for their efforts in acknowledging the need for more diversity in clinical trials and research, and for using a multipronged approach to thoroughly understand the critical barriers that seem to be precluding adequate diversity in trials that is reflective of society.

It is refreshing to see this report has successfully drawn out some very key issues that may be contributing to the lack of diversity in clinical trials, such as awareness. Identification of the issues is the first step to making change.

From my perspective, some highlights that resonate include:

- The need for open communication and dialogue with ethnic minorities to address the lack of trust and improve understanding of the purpose and process of the trial
- The recognition of the need for strong collaboration, using trusted sources in the community to act as a bridge and leveraging relevant communication channels and formats
- The imperative to take the time to recognize and respect cultural nuances and cultural stigmas and stereotypes centered around health, the importance of family and community, and who needs to be involved in the decision-making process
- Acknowledgement of financial and physical limitations that may not be present in the mainstream population and being open to considering other locations or centers that may allow a greater diversity of participants
- Recognition that support, education and awareness need to be focused not only on potential patients/participants but also the physicians/clinicians, and an understanding by each party as to the important role they can potentially play in positive clinical trial representation and outcomes

As a patient, I would appreciate it if any or all of the above, is always kept front of mind, as it will allow greater empathy, cultural competency and understanding among those who are designing approaches or engagement strategies for clinical trials, and a greater likelihood for patients like me to be included, to contribute and to have a voice.

This diversity in clinical trials research is a needed and important first step to shine a light on the structural issues and ensure that there is greater awareness of the need for increased ethnic diversity in clinical trial participation. However, it also goes one step further in that it provides consistent insights that highlight some of the key barriers precluding clinical trial participation that can be addressed or further explored to allow participation to be truly reflective of the community in which we live.

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Key Insight >
Key Insight >
Key Insight >

SEE FULL CONTENT STREAM

Minnie Baylor-Henry

Minnie Baylor-Henry, JD, is currently President of B-Henry & Associates, LLC, and executive partner of YourEncore, a leading provider of proven expertise to the life sciences and consumer goods industries. Previously, she was the worldwide Vice-President of regulatory affairs-medical devices for Johnson & Johnson. She also serves on Howard University's Board of Trustees.

* * *

As we face the many complexities of a public health crisis brought about by a global pandemic, Black and Brown people, along with other disaffected people globally, are watching as society confronts the reality of many years of healthcare inequalities. Society is now forced to grapple with the intersection of culture, race and class and the impact this has had on our fragile healthcare infrastructure. The pandemic, layered on top of the countless incidents of social unrest, has brought to the forefront, the reality of the many inequities in our healthcare systems.

When questions arise regarding the reluctance of Black and Brown people, for example, to trust the healthcare systems and allow a vaccine to be administered, historic mistreatment is uppermost in their mind. Have Black and Brown people been denied opportunities to participate in clinical research regarding treatments for diseases that primarily impact their communities? Why are Black and Brown people being asked to put aside their mistrust and believe that this year, at this time, everyone will receive equitable treatment and consideration? Why have there been minimal efforts to understand how to reach diverse communities in order to assure a better understanding of health concerns? How does the healthcare system restore trust in these disenfranchised communities after they've endured years of being damaged physically and emotionally?

This report provides some global insights into the issues facing Black and Brown communities that are now at a crossroads regarding how to respond to an unprecedented public health crisis. The report touches on the impact of structural, cultural and institutional biases and the resulting challenges for healthcare providers going forward. However, more research is needed if we are going to tackle the many injustices affecting all disadvantaged people globally.

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What's In The Report

A brief overview of the insights we've gained and the methods leveraged to produce this report.

Read more ›

SEE FULL CONTENT STREAM

Dr. Valerie Stone

Valerie Stone, MD, MPH, is Vice-Chair for diversity, equity, and inclusion of the Department of Medicine at Brigham and Women's Hospital. Dr. Stone is an academic general internist as well as an infectious disease specialist and is a Professor of Medicine at Harvard Medical School.

Black, Indigenous and People of Color (BIPOC) are disproportionately affected by every major disease. This is true of diabetes mellitus, hypertension, cardiac disease, and cancer—the major chronic illnesses of our time. It is equally true of the life-threatening infectious diseases—tuberculosis and HIV, and now COVID-19. In contrast, however, BIPOC are underrepresented in clinical trials for the study of new treatments and preventive interventions for all these diseases. While this has been a concern for decades, the confluence of the COVID-19 pandemic's inequitable impact on communities of color and our collective enhanced commitment to racial justice has made this a more urgent concern.

We know that the underrepresentation of BIPOC in clinical trials is at least in part a result of mistrust due to historical abuses of Black and Brown people in research and in clinical care. We also know that some of the underrepresentation is due to continued inequities and racial injustices in healthcare and beyond. Given this, if we hope to improve the representation of BIPOC in clinical trials, we must make active efforts to "move the needle." Herein, we share important new findings from quantitative and qualitative research among diverse community members and diverse physicians about what it will take to enhance clinical trial heterogeneity. This report provides concrete ways that researchers and industry can become more trustworthy—by partnering with diverse communities in new and authentic ways and investing in building research capacity in diverse communities. We hope that you find this information of value to you in your work.

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some of the obstacles...."
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diabetes mellitus, hypertension...."
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What's In The Report

INTRODUCTION

What’s In The Report

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From both an ethical and scientific perspective, clinical research participation should benefit and represent all individuals. However, **for the 48 novel drugs approved in the United States in 2019, it is clear that Black patients were not adequately represented, whereas white participants were overrepresented.**[1,2]

BLACK PARTICIPANTS

9% IN TRIALS VS **12.2%** IN GENERAL POPULATION

WHITE PARTICIPANTS

72% IN TRIALS VS **60.1%** IN GENERAL POPULATION

There are also differences by indication, for example, in oncology clinical trials, where Black and Latinx trial participants have been consistently underrepresented based on cancer incidence and mortality in the United States.[3]

Science and society do recognize the importance of diverse representation in clinical trials, with inclusive health being a keystone to a just, equitable society. In addition, a study population lacking diversity weakens the ability of investigators to adequately understand the safety, efficacy, effectiveness and value of the potential new medication in the general population. The issues that persistently impact study populations are complex, involving a range of inequities in both opportunity and access.

Today, the pharmaceutical industry is gaining a much better grasp of the social determinants of health and health outcomes. Candid discussions between academia, industry, patients, advocacy organizations, physicians and communities provide insight into ways to effectively improve diversity in clinical research.

In order to make this a reality, we must truly commit to collaboratively engaging with patients from a diversity of races, ethnicities and cultures. Only then can we understand the barriers they experience and effectively mitigate them. Diversity and inclusion are possible for clinical trials—but our success depends on our continued, collective focus.

This Parexel report is a topline summary of an extensive, global, quantitative survey, focus group sessions, interviews and Patient Advisory Council meetings that called on patients, members of the public and physicians to provide their perspectives on clinical-trial diversity. Research was a collaborative effort produced with the aim of understanding the critical barriers to research access and obtaining guidance on how to successfully overcome them. To produce this report, the following methods were leveraged:

Research Method	Participation	Countries
Video and audio one-on-one interviews	40 Black, Latinx and Asian members of the public (13.5 hours)	UK and USA
Physician focus groups	13 Black and Latinx physicians across 2 focus groups (8 hours)	USA and Canada
Parexel Patient Advisory Council	7 Black, Latinx and Asian participants (4 hours)	USA, Italy, Australia and UK
Quantitative survey	1,945 respondents across a broad range of racial and ethnic groups	USA, Canada, UK, Australia, France, Hungary, Italy, Mexico, Poland and Spain

KEY TAKEAWAY

This report is the result of a series of studies conducted with patients, physicians, prospective clinical-trial participants, active and former clinical-trial participants. The findings of this research identify key barriers to clinical-trial inclusivity while also offering specific actions industry can take to address inequities in healthcare and clinical study access.

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1. Woodcock J, Anagnostiadis E, Lolic M. Center for Drug Evaluation and Research, U.S. Food & Drug Administration. (2020). 2019 Drug Trials Snapshots Summary Report.
2. Population Distribution by Race/Ethnicity (2019). https://www.kff.org/other/state-indicator/distribution-by-raceethnicity/. Accessed January 8, 2021.
3. Loree JM, Anand S, Dasari A, et al. Disparity of race reporting and representation in clinical trials leading to cancer drug approvals from 2008 to 2018. *JAMA Oncol*. 2019;5(10):e191870.

NEXT CHAPTER
Building Relationships & Trust

KEY FINDINGS

Building Relationships & Trust

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Research results highlight a significant lack of trust in medicine in many communities, particularly related to the pharmaceutical industry. Patient concerns about receiving a placebo, negative medical events in history and a perceived lack of the physician's understanding of some racial and ethnic groups have all been attributed to these **feelings of mistrust and skepticism by participants:**

> “I would want to do a lot of research before doing a clinical trial. I think people of color have to be very careful. I know how Black women were treated and studied without previous consent in the past. I would personally be hesitant in joining a clinical trial.
>
> **Member of the Public, Interviewee**

Such a view was also reflected in a physician's experiences:

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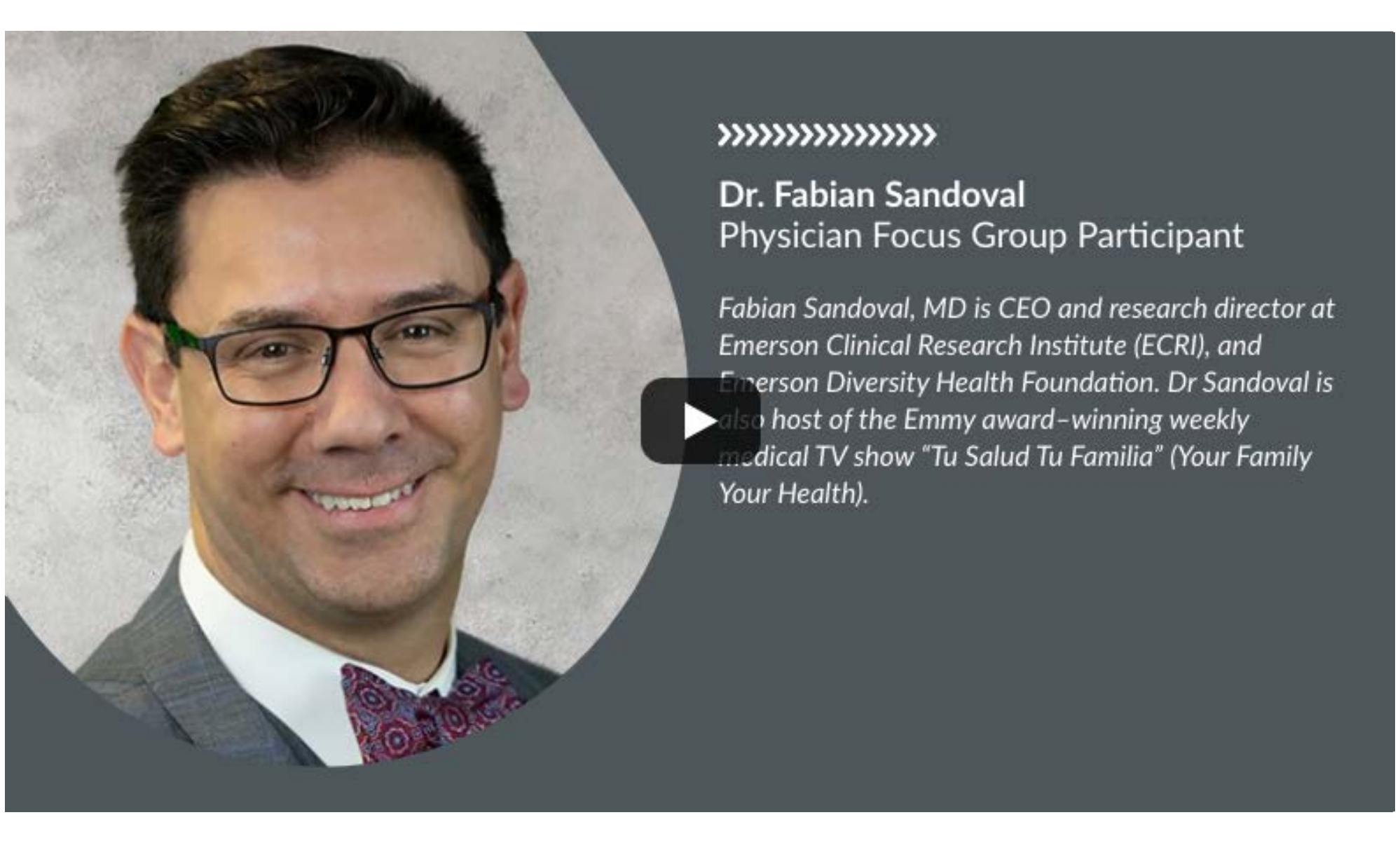
Dr. Winfred Williams
Physician Focus Group Participant

Winfred Williams, MD, is the Associate Chief of the Massachusetts General Hospital (MGH) Division of Nephrology and founding director of the MGH Center for Diversity and Inclusion.

Building trust is therefore critical to engagement in clinical research and will require enhanced patient engagement activities by site personnel:



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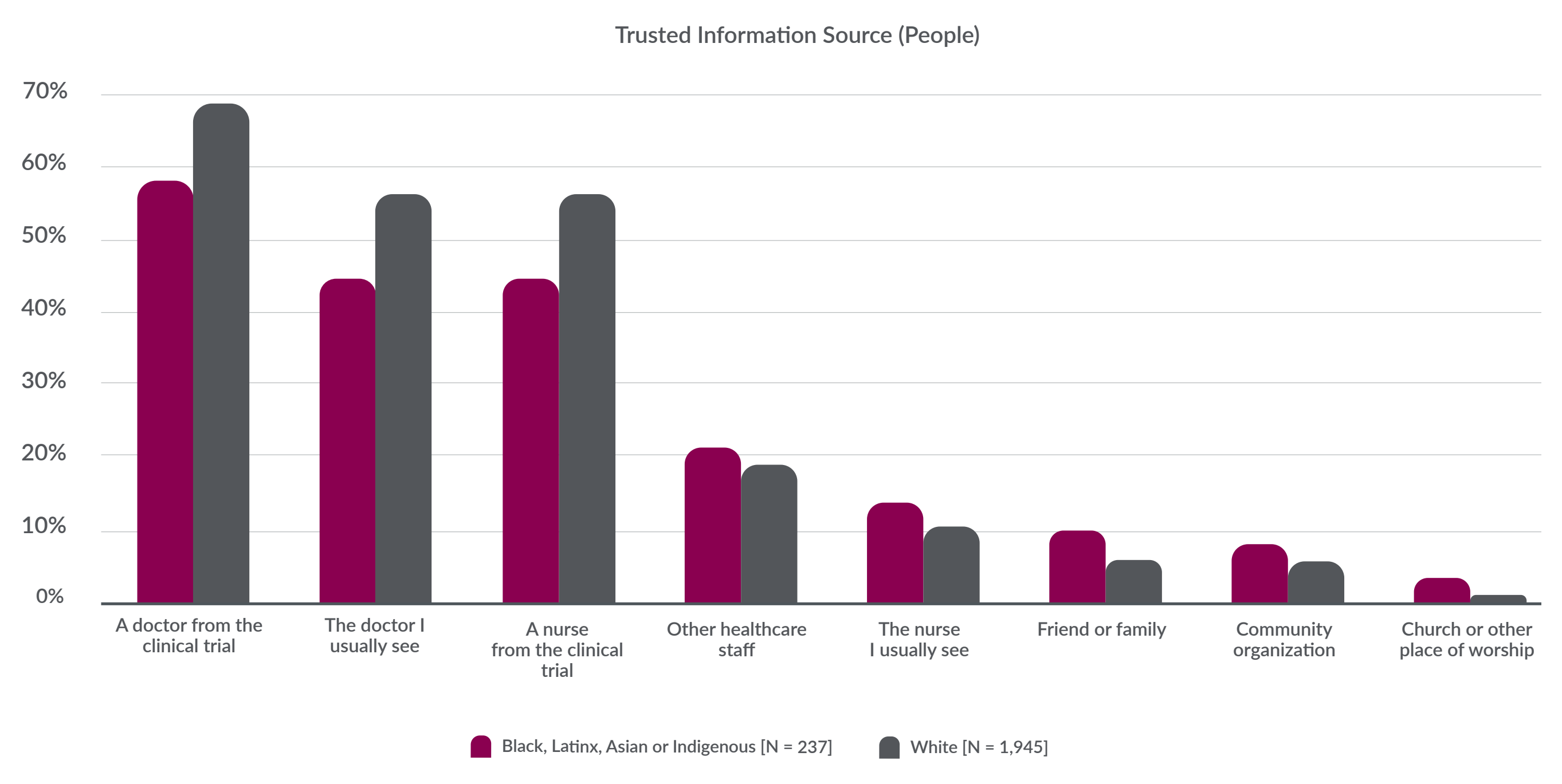
Dr. Fabian Sandoval
Physician Focus Group Participant

Fabian Sandoval, MD is CEO and research director at Emerson Clinical Research Institute (ECRI), and Emerson Diversity Health Foundation. Dr Sandoval is also host of the Emmy award-winning weekly medical TV show "Tu Salud Tu Familia" (Your Family Your Health).

In the global survey, **doctors** were regarded as the **most trusted source of clinical-trial information**

(**58% of Black, Latinx, Asian and Indigenous respondents [N = 237]** compared to **69% of white respondents [N = 1,945]**):



Supplementary to this, participant interviewees and Patient Advisory Council members alike expressed that engagement with trusted community advocates to share research information and education is critical to success:

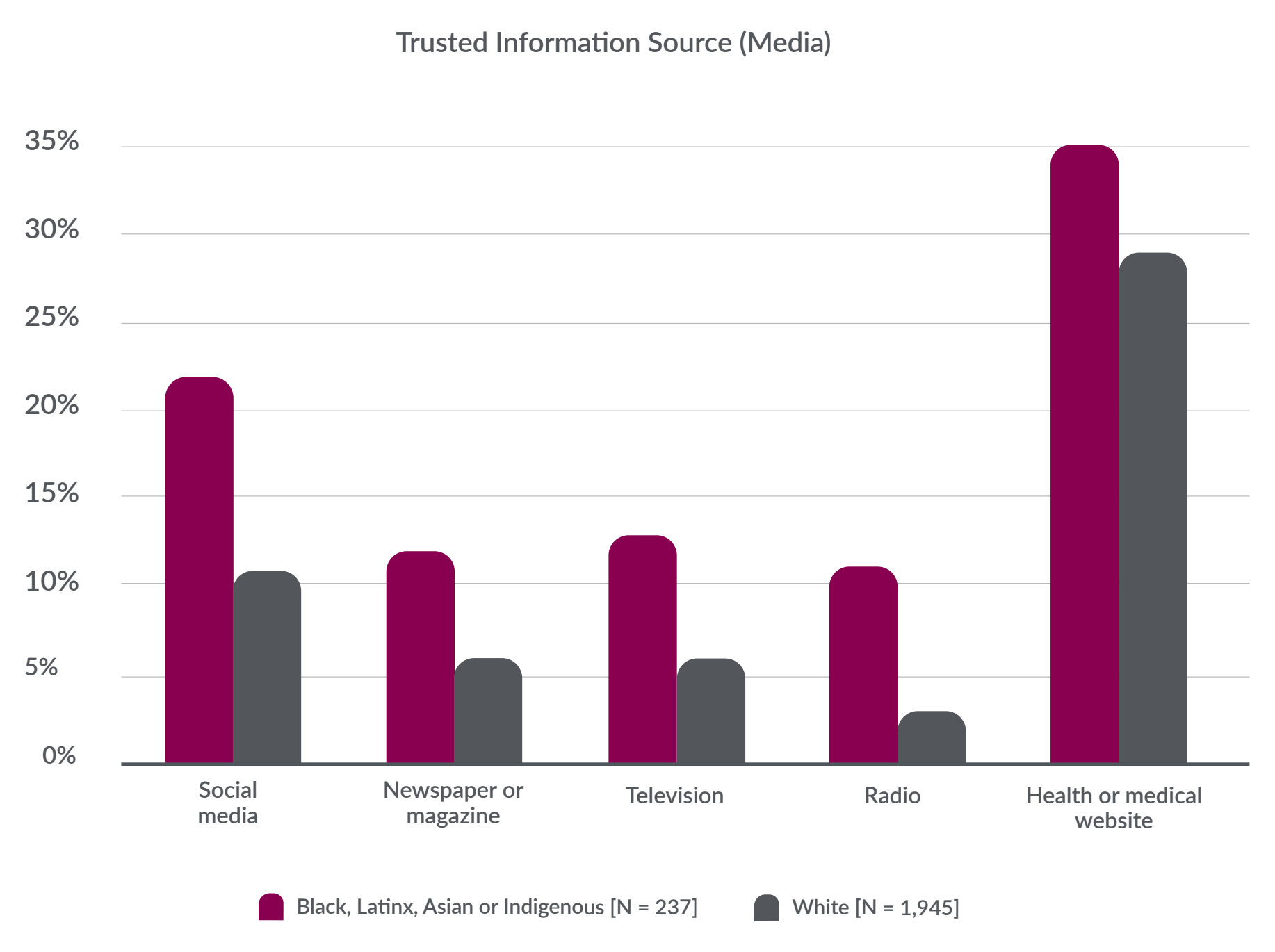
> “We have to meet patients where they actually are; they may not be in a medical center. You may have to go to a community center, a religious organization or local barbershops. If we train some community advocates, people who are in the community every day and who are trusted, you would be surprised at the level of complexity of conversations that happen.
>
> **Yasmeem Watson, Patient Advisory Council Member**

Family opinion was also viewed as important, with one physician explaining:

Dr. Valerie Stone
Physician Focus Group Participant

Valerie Stone, MD, MHP, is Vice-Chair for diversity, equity, and inclusion of the Department of Medicine at Brigham and Women's Hospital (BWH). Dr. Stone is an academic general internist as well as an infectious disease specialist and is a Professor of Medicine at Harvard Medical School.

And, though outreach via advertising was not rated highly by any survey respondents, when it is utilized, preferences are as follows:



KEY TAKEAWAY »»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»

Results show a multipronged approach to promoting clinical research education through trusted site staff, advertising channels and community advocates will benefit broader awareness understanding and, in turn, improve research access.

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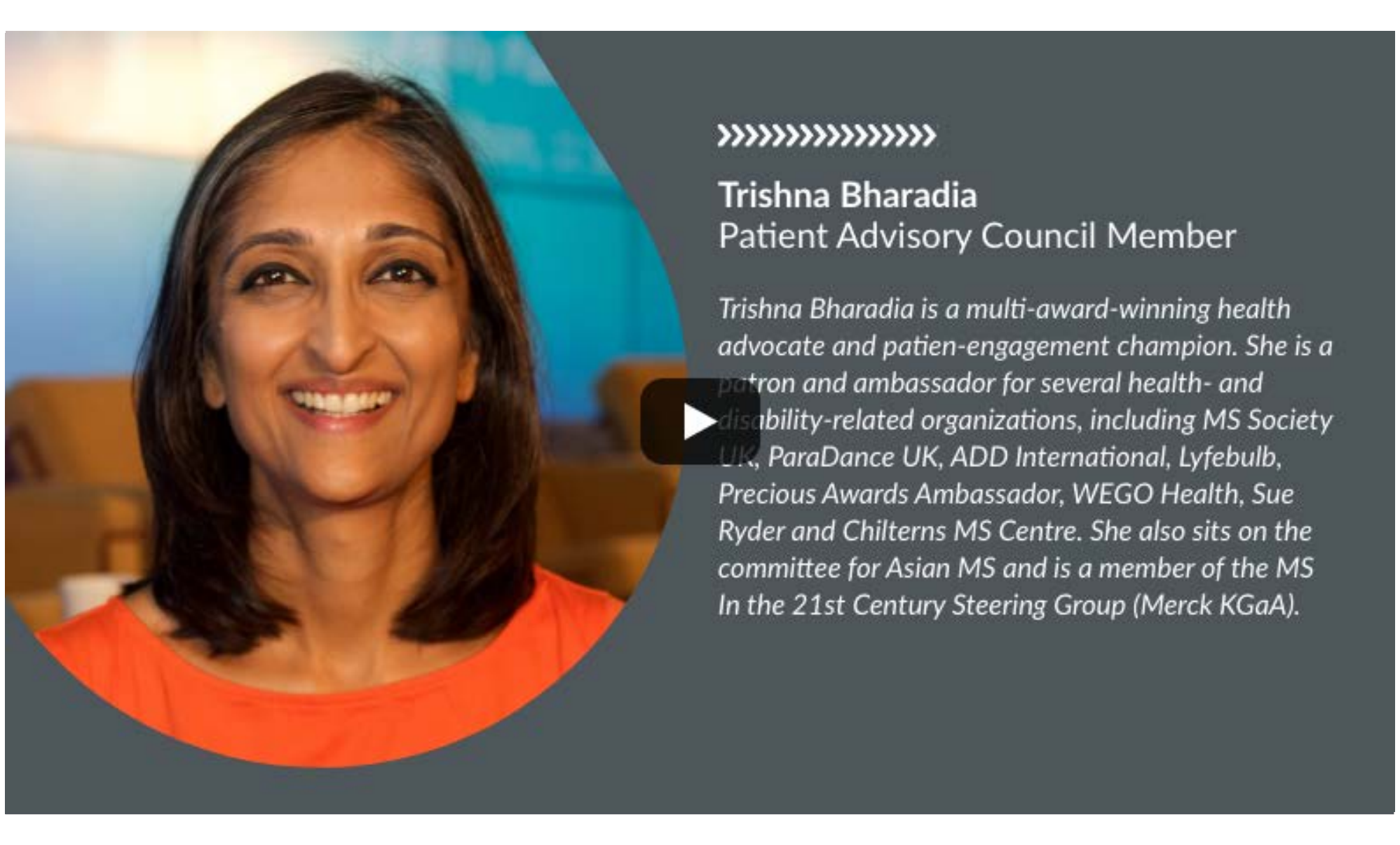

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Trishna Bharadia
Patient Advisory Council Member

Trishna Bharadia is a multi-award-winning health advocate and patien-engagement champion. She is a patron and ambassador for several health- and disability-related organizations, including MS Society UK, ParaDance UK, ADD International, Lyfebulb, Precious Awards Ambassador, WEGO Health, Sue Ryder and Chilterns MS Centre. She also sits on the committee for Asian MS and is a member of the MS In the 21st Century Steering Group (Merck KGaA).

»» Building Relationships Between Patients and Site Staff

During both physician focus groups and Patient Advisory Council discussions, patients being treated by site staff of the same race, ethnicity or cultural background was viewed as being a very important aspect of increasing diversity in clinical research but one that can prove difficult to achieve.

»»»»»»»»»»»»»»

Dr. Winfred Williams
Physician Focus Group Participant

Winfred Williams, MD, is the Associate Chief of the Massachusetts General Hospital (MGH) Division of Nephrology and founding director of the MGH Center for Diversity and Inclusion.

Interestingly, interviews with members of the public and quantitative research results indicated that this was a far less significant consideration, with a combined 20% of Black, Latinx, Asian and Indigenous participants globally compared to 11% of white participants citing it as important.

> “I don't believe ethnic background has any influence in qualifications or anything to do with my confidence in the safety of the study.
>
> **Member of the Public, Interviewee**

The reason for such differences in opinion was not explored in the research. However, it could perhaps be a result of those with greater experience with medical interactions citing this as a key consideration. Partnering with sites with greater staff diversity could therefore help address the current gap in research participation among some racial and ethnic groups, and the issue certainly warrants further exploration.

When it is not possible for patients to be treated by site staff from a similar racial ethnic, and/or cultural background, it is critical for staff to understand and accommodate differences in cultural norms. This helps patients, caregivers and families feel comfortable, build trust and ensure that they are making treatment decisions that are right for them.

> “There are cultural differences that are not accepted or even considered within the medical community. Sometimes, entire families come to an appointment because everyone wants to be involved in medical decisions. It's just different things that you have to pay attention to.
>
> **Yasmeem Watson, Patient Advisory Council Member**

KEY TAKEAWAY »»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»

Respondents to this research highlighted a preference by many patients for being treated by someone who looks like them. Where this is not possible, some site staff may benefit from cultural competency training to optimize the patient experience.

»»

NEXT CHAPTER
COVID-19 Perceptions

KEY FINDINGS

COVID-19 Perceptions

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Physician focus group discussions revealed low expectations for COVID-19 vaccine trial participation in diverse communities by most participants, with a lack of trust in the pharmaceutical industry again highlighted as a key barrier, in addition to an ongoing stigma around infectious diseases. However, 45% of quantitative research respondents from non-white communities globally stated that they would consider joining a COVID-19 trial, with many attributing this willingness to a desire to help others. Interestingly, a slightly lower proportion of white respondents (39%) expressed a willingness to join a COVID-19 trial.

WILLINGNESS TO JOIN A COVID-19 TRIAL.

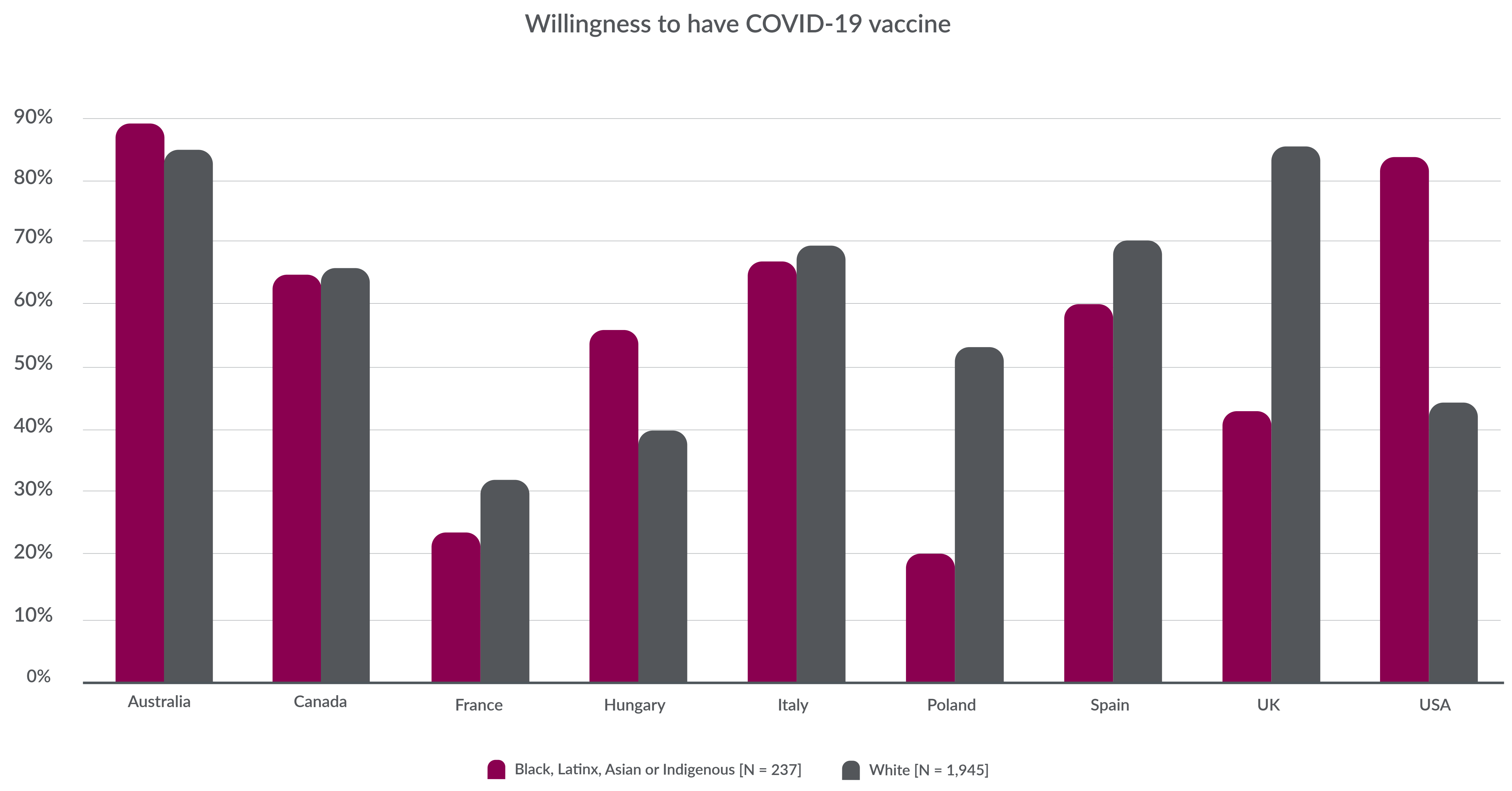
> I wouldn't mind joining a COVID-19 trial because I took the flu vaccine. I think some people are scared to take vaccines because they think it will make them feel ill. (Worse?)
>
> **Member of the Public, Interviewee**

Physicians also stated that they expected low COVID-19 vaccine uptake based on trends of low levels of flu vaccination, especially among the Black and African American community. When asked, 60% of non-white respondents expressed openness to a vaccine once it's available compared to 55% of white participants—although a majority didn't want to be the first to receive it.

OPENNESS TO RECEIVING A COVID-19 VACCINE

> I would probably use the COVID-19 vaccine if it actually works and there are no side effects. I would be very cautious of it though.
>
> **Member of the Public, Interviewee**

Where the gap between physician and nonphysician perceptions originates from is unclear. However, it will be important to work with both groups to provide education and opportunities to join trials so that COVID-19 research and vaccination are optimized in communities where participation has historically been low. This will also vary per country depending on the public's general perception of clinical research and vaccines.


Willingness to have COVID-19 vaccine

As shown in the table above, there are some countries where there were similar attitudes to receiving a COVID-19 vaccine regardless of race or ethnicity, whereas others, such as the UK and Poland, showed a vast difference between Black, Latinx, Asian or Indigenous respondents' vs. white respondents' willingness to receive a COVID-19 vaccine when available (42% vs. 85%, respectively, in the UK and 20% vs. 53%, respectively, in Poland).

Conversely, we see a greater number of non-white respondents in the USA willing to receive a vaccine when available, with comments from respondents citing the seriousness of the pandemic and need to protect themselves from it as primary reasons. Despite this stated willingness, in the USA initial vaccination data indicates that a higher proportion of white citizens have been vaccinated to date than any other community.[4] This further highlights the risk of significant access disparity, showing the need to be intentional in supporting accelerated vaccine access to all communities.

---

[4] Rachael Dottle, Akayla Gardner, Jeff Green, Angelica LaVito, Marie Patino, Andre Tartar, Alexander McIntyre and Aaron Kessler. Bloomberg. Not One U.S. State Has Vaccinated 20% of Its Black Population: Covid-19 Tracker. https://www.bloomberg.com/graphics/covid-vaccine-tracker-global-distribution/us-vaccine-demographics.html. Accessed 18 February 2021.

NEXT CHAPTER
Research Awareness and Understanding

KEY FINDINGS

Research Awareness and Understanding

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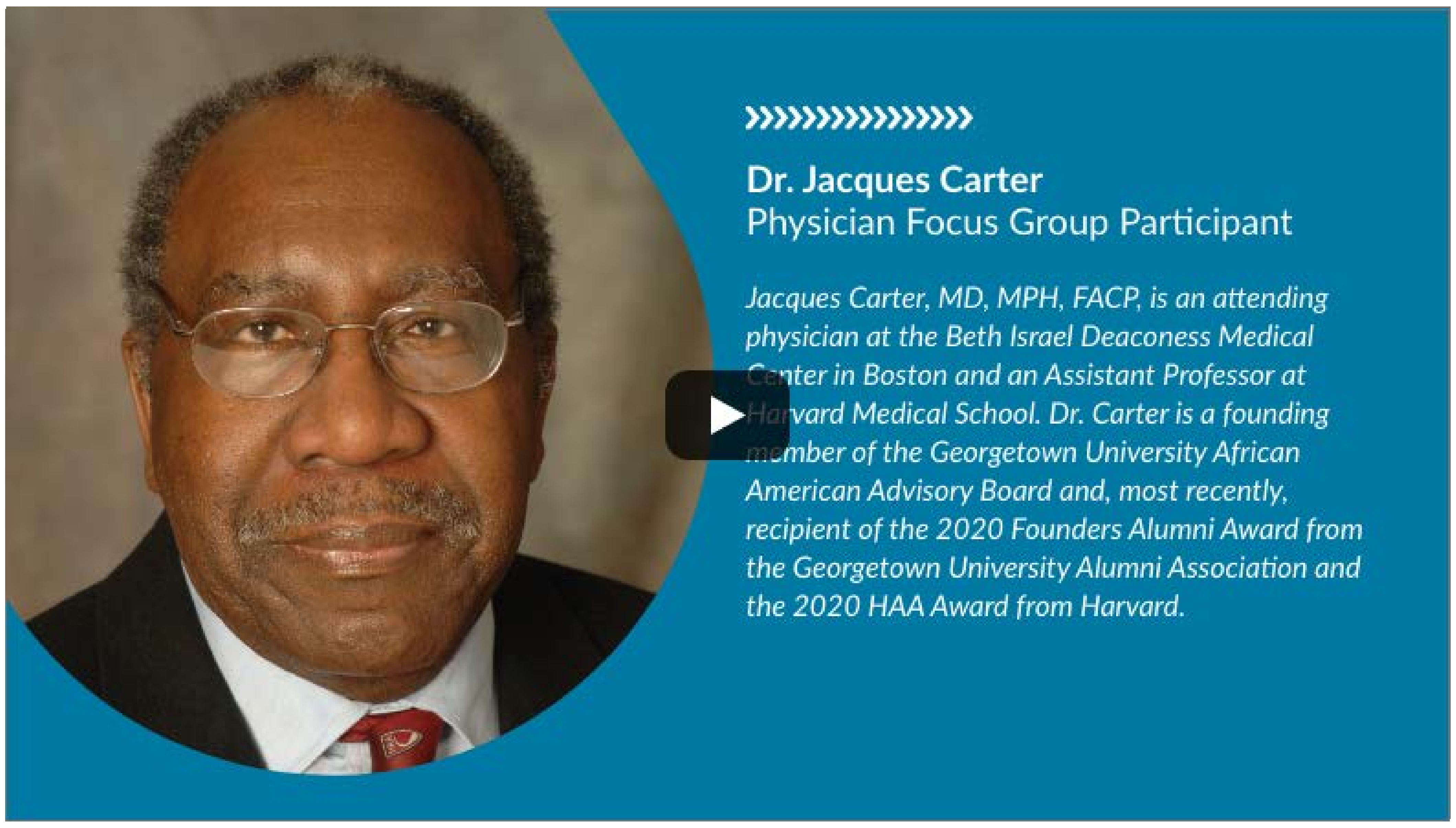
Generally, clinical research awareness, understanding and trust are all low among research participants, something common across the world prior to the race for a COVID-19 vaccine. The pandemic has put clinical research under a microscope, especially in places like the United States, where mixed messages related to the virus, the vaccine and protective measures have been distributed widely.

This awareness and understanding also affects different communities' perceptions of physicians going into research:



Dr. Jacques Carter
Physician Focus Group Participant

Jacques Carter, MD, MPH, FACP, is an attending physician at the Beth Israel Deaconess Medical Center in Boston and an Assistant Professor at Harvard Medical School. Dr. Carter is a founding member of the Georgetown University African American Advisory Board and, most recently, recipient of the 2020 Founders Alumni Award from the Georgetown University Alumni Association and the 2020 HAA Award from Harvard.

KEY TAKEAWAY

An increased focus on clinical trials and research presents an opportunity to educate people about participating in clinical trials and the potential benefit these trials have in finding new medications and treatments for COVID-19 and other diseases.

NEXT CHAPTER
Disease Perceptions

KEY FINDINGS

Disease Perceptions

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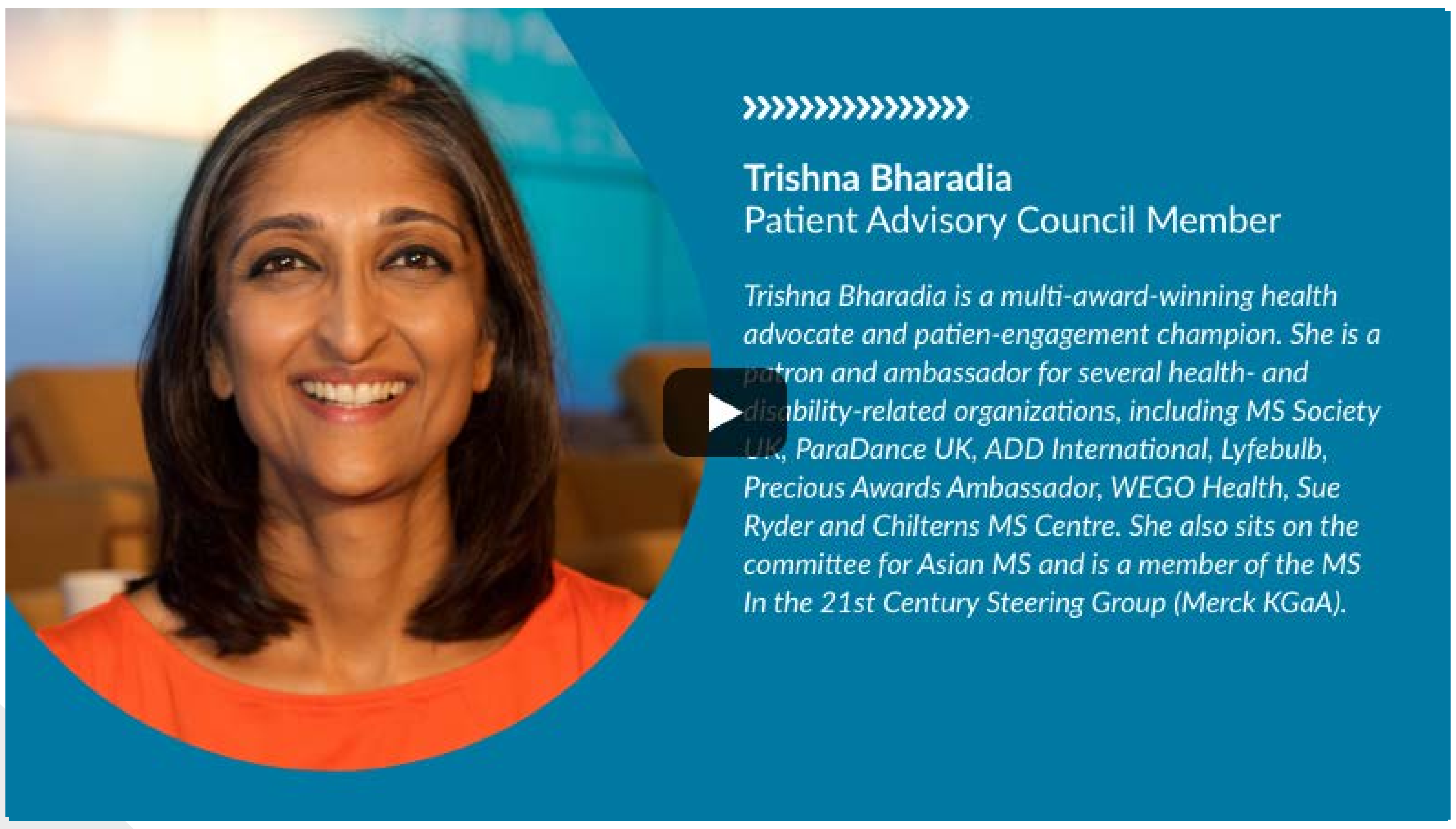
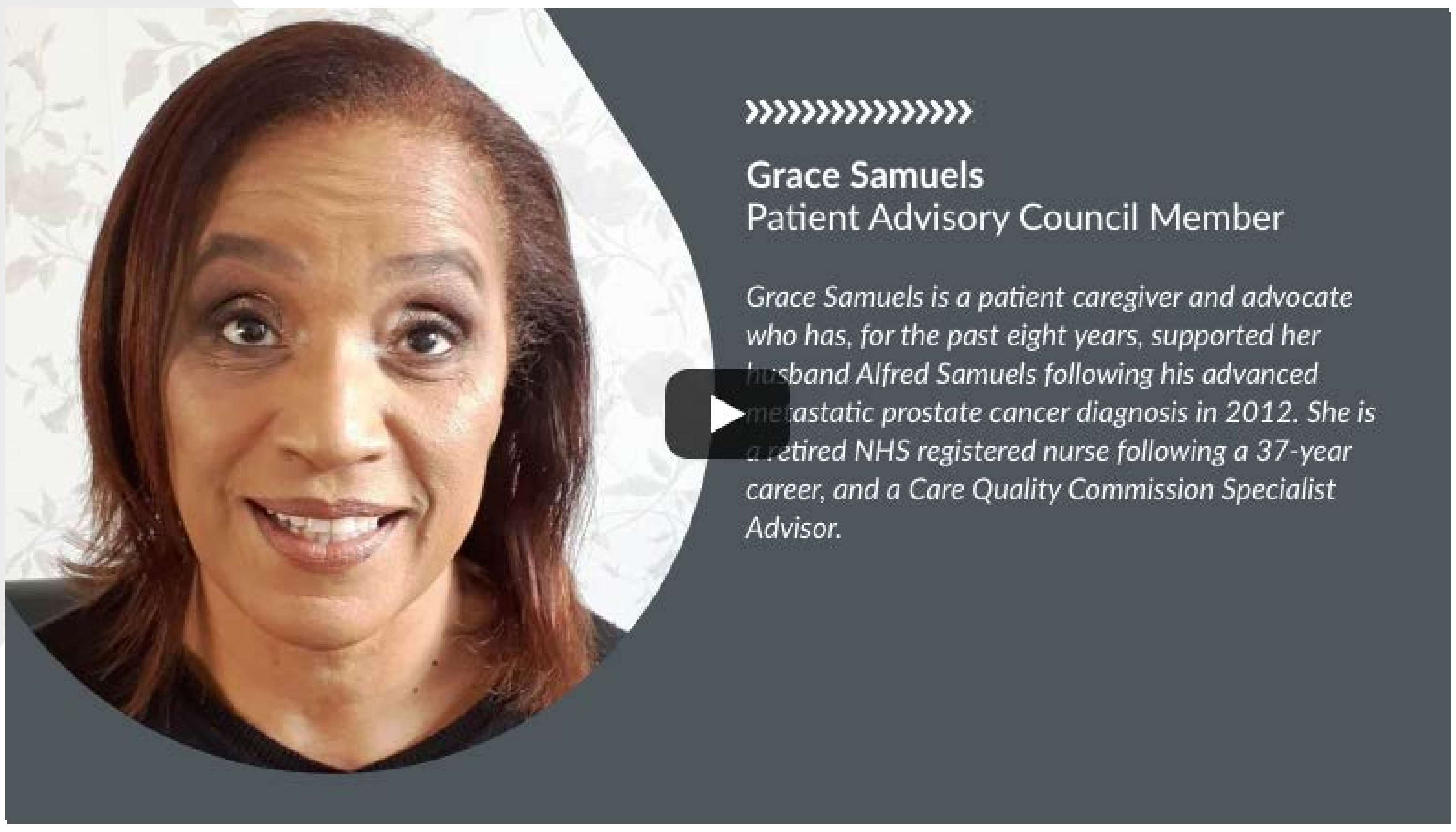
Secrecy about illness was reported by participants from both Black and South Asian backgrounds, which they explained can impact how patients and their families seek medical treatment and the willingness to take part in clinical research.



Trishna Bharadia
Patient Advisory Council Member

Trishna Bharadia is a multi-award-winning health advocate and patien-engagement champion. She is a patron and ambassador for several health- and disability-related organizations, including MS Society UK, ParaDance UK, ADD International, Lyfebulb, Precious Awards Ambassador, WEGO Health, Sue Ryder and Chilterns MS Centre. She also sits on the committee for Asian MS and is a member of the MS In the 21st Century Steering Group (Merck KGaA).



Grace Samuels
Patient Advisory Council Member

Grace Samuels is a patient caregiver and advocate who has, for the past eight years, supported her husband Alfred Samuels following his advanced metastatic prostate cancer diagnosis in 2012. She is a retired NHS registered nurse following a 37-year career, and a Care Quality Commission Specialist Advisor.

KEY TAKEAWAY

Perceptions of illness can vary between cultures, so understanding these differences is an important step to providing trial information and support in a sensitive manner.

NEXT CHAPTER
Practical Barriers

KEY FINDINGS

Practical Barriers

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Qualitative results from Patient Advisory Council and physician focus groups highlighted that clinical trial participants often need to receive information in their primary language and, as with all patients, simple, nontechnical terms. The use of videos and infographics will also aid in building trust and understanding.

As one patient told us:

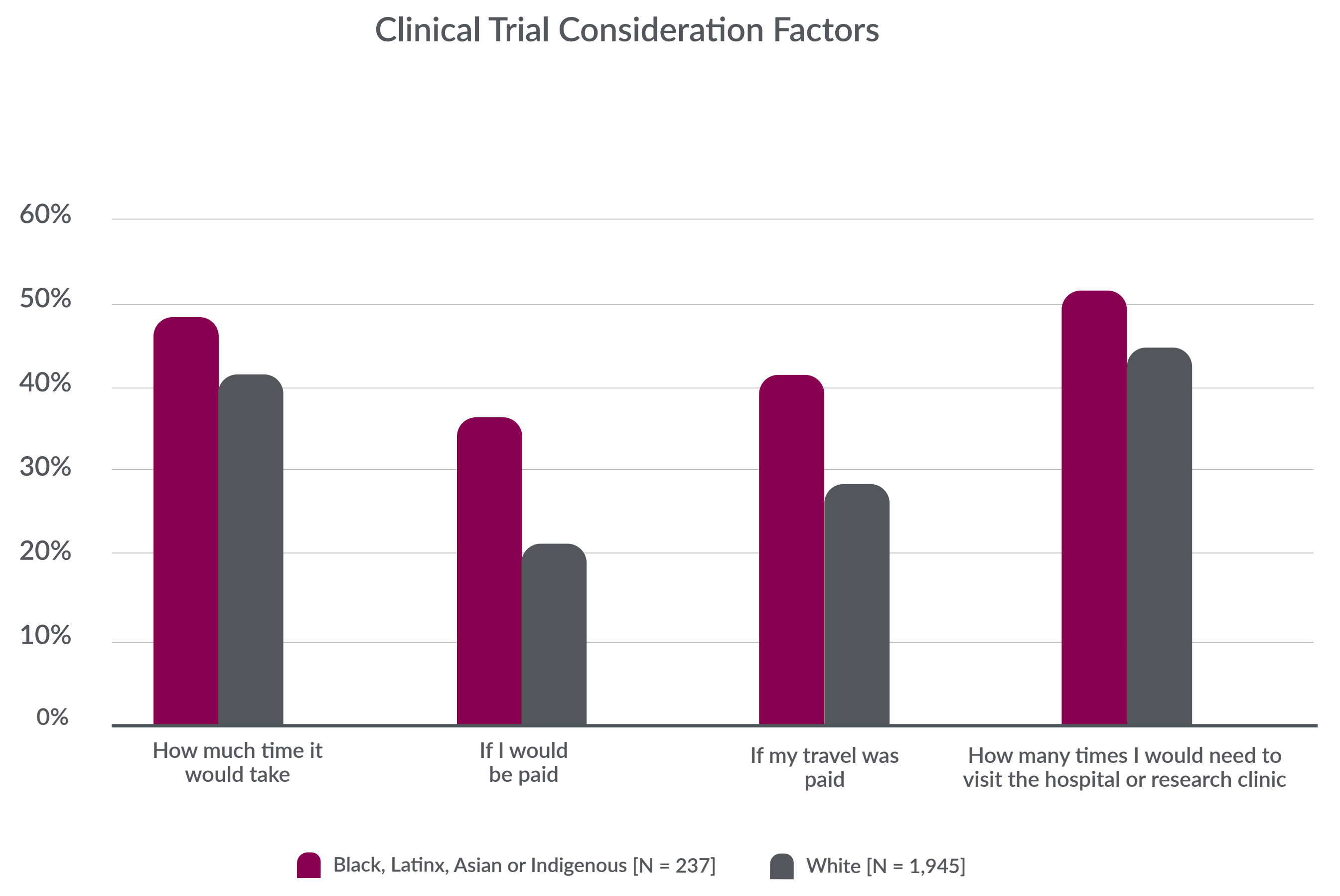
> “ In Queens, New York City, we have 250 languages. We do not expect every hospital to have all those translations, but we can at least pick 5 or 10 major languages within the areas where you want to reach out and bring diversity into trials. Yes, it’s going to be more expensive, but the value that is going to bring and the respect that it is showing to this community means that it’s explained in a way that someone can understand.
>
> **Ivis Febus-Sampayo, Patient Advisory Council Member**

Ivis Febus-Sampayo is a two-time breast cancer survivor as well as a patient advocate and Senior Director of Programs at SHARE Cancer Support. Ms. Febus-Sampayo is a board member of the National Board for Certified Counselors (NBCC) and is involved in both local and national committees. She has won local and national recognition as well as a number of awards through her work at SHARE.

KEY TAKEAWAY

Offering clinical trial information in plain, easy to understand and appropriate languages is something industry can do swiftly to promote better research access.

Financial and other practical barriers, such as provision for childcare during visits, also pose significant challenges to trial participation for many patients, regardless of race or ethnicity. That said, such barriers were highlighted in the quantitative research by a greater proportion of Black, Latinx, Asian and Indigenous participants than white participants. For example, the number of required study visits was cited as the greatest barrier, followed by visit duration and payment for travel and for participation:



As one participant stated:

> “ Clinical trials, especially those within minorities and in certain areas, need to be accessible for those with limitations, both physically and financially. Many forget that even in this day and age not everyone has access to the internet or public forms of transportation.
>
> **Member of the Public, Survey Respondent**

These barriers do not only affect the patient but also the caregiver. Caregivers are an often under-considered yet vitally important element to the success of any clinical trial and act as trusted advocates in the clinical trial process.

Sheila Khawaja
Patient Advisory Council Member

Sheila Khawaja is a rare disease patient advocate and World Alliance of Pituitary Organizations board member as well as a EURODIS fellow. Most recently Ms. Khawaja joined the Patient Advisory Board at Sage Publishing for the journal Therapeutic Advances in Drug Safety to support and advise the journal’s editorial board on lay summaries and related topics.

KEY TAKEAWAY

Reducing or eliminating practical and logistical challenges could have a significant impact on improving research across patient groups.

Reimbursement for time and travel is widely accepted by ethics committees/institutional review boards but is not always included as part of trial strategies. Similarly, decentralized clinical trials (DCTs) that center research around patient convenience and delivery in their home or community are increasing in popularity but are not yet the norm.

To successfully improve research and address the lack of adequate diverse representation in clinical research for many of those who are most affected by the illnesses being studied, both of the strategies mentioned above are recommended.

> “ Some women, some African American women, don’t have time to come to chemo because they have children at home that have to be cared for. They don’t have time to come to medical appointments. They would love to be cured and love to be healed, but sometimes it is beyond their control. If you’re just saying, ‘Okay, they can’t come to the appointment, moving on to the next patient, that’s not going to help anyone. We’ve got to get behind the problem, to understand and solve the problem.
>
> **Yasmeem Watson, Patient Advisory Council Member**

NEXT CHAPTER
Decentralized Clinical Trials (DCTs)

KEY FINDINGS

Decentralized Clinical Trials (DCTs)

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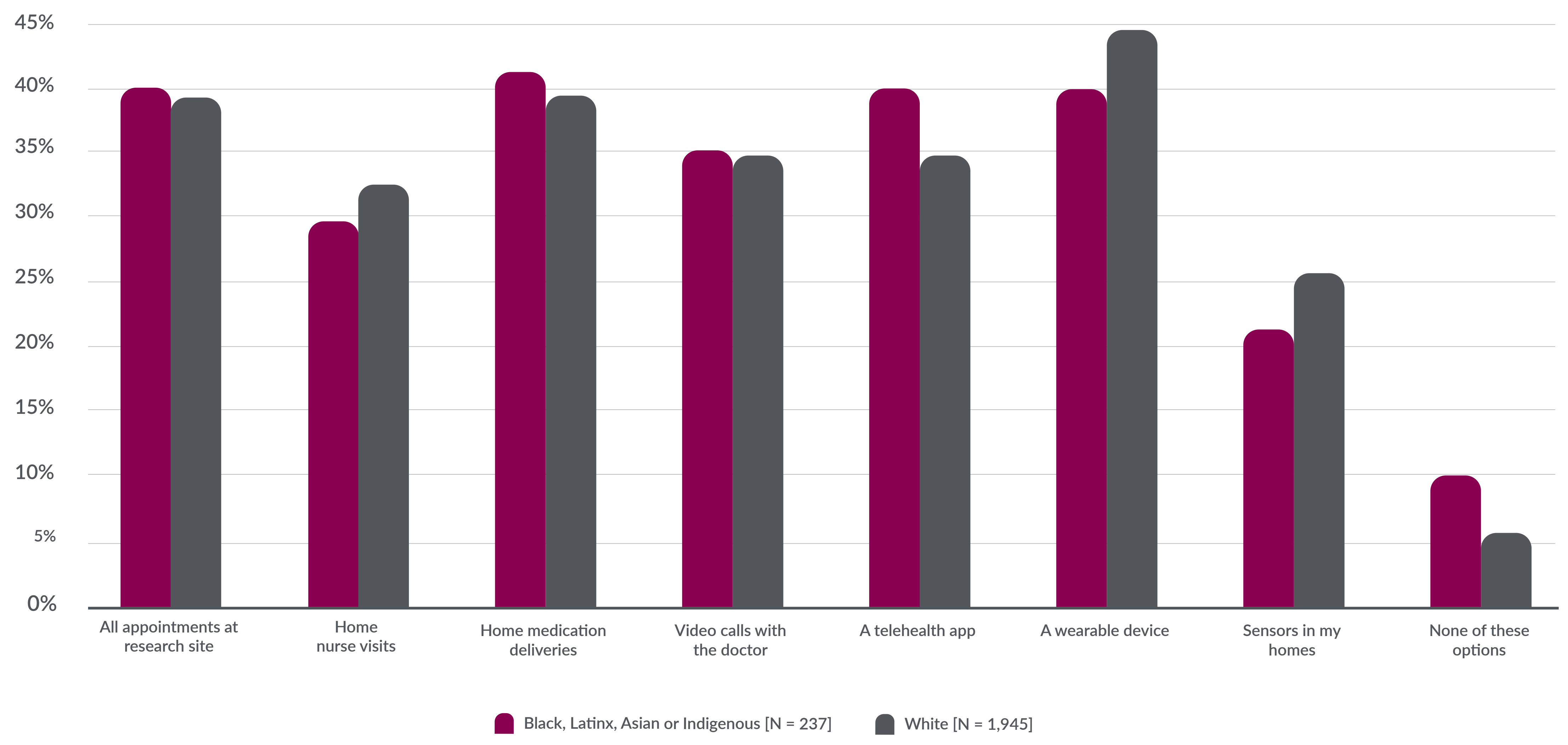
As previously mentioned, DCTs can help overcome many barriers to research involvement. However, our experience shows that the needs and preferences of patients and caregivers must be carefully considered on a study-by-study basis. The disease in question and the daily challenges it brings have a huge impact on the individual home-based strategy that's to be deployed. That said, quantitative research results showed little difference between respondent groups in terms of preferences of DCT options, with **home medication deliveries (42%), phone apps (40%) and wearables (40%) being the most interesting options, though a similar proportion also preferred in-hospital involvement (40%):**

If you were thinking about joining a clinical trial, which options would you prefer?



During the qualitative research, the aforementioned secrecy surrounding illnesses for many communities was cited as a potential barrier to home-based participation:

> "Many haven't told their extended family; they haven't told the wider community. So if they were taking part in a decentralized clinical trial, that could expose them. Many don't want healthcare professionals coming to their houses because then neighbors will know something is wrong.
>
> **Trishna Bharadia, Patient Advisory Council Member**

KEY TAKEAWAY »»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»»

DCTs should be approached with flexibility and an understanding of the needs of different communities.

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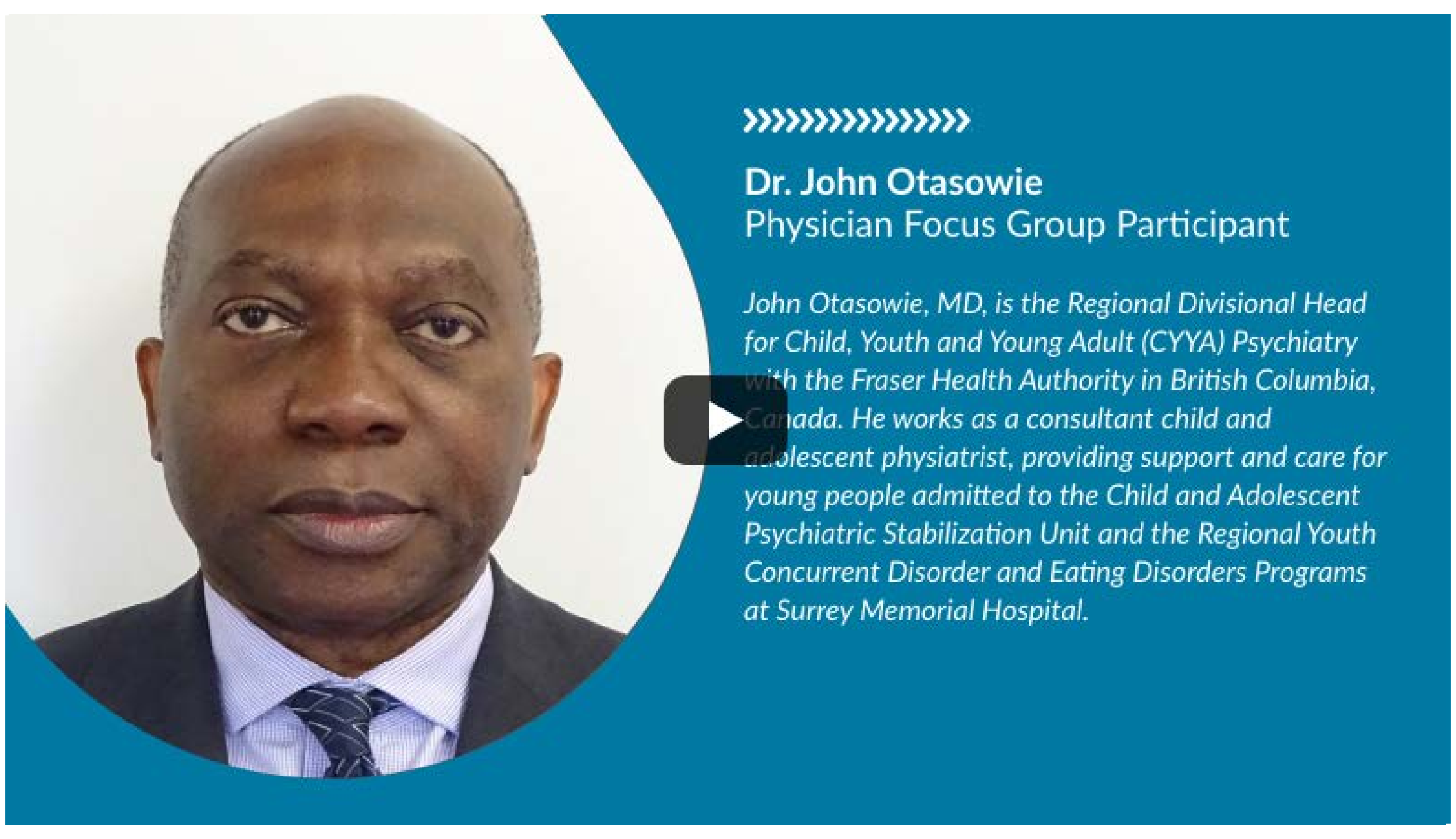
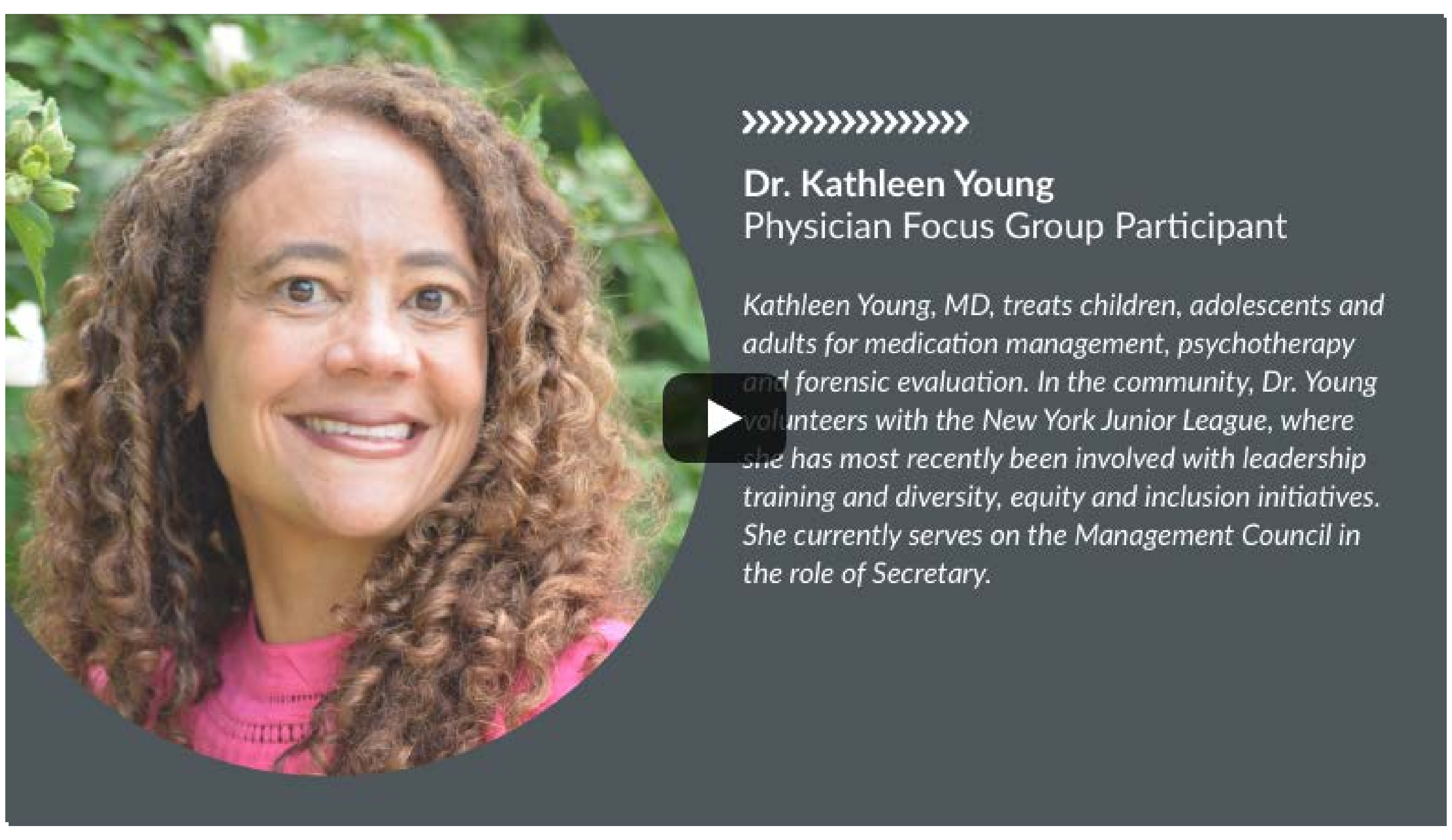
This will ensure that the benefit of reduced patient and caregiver burden is not in conflict with their needs. An adaptive, flexible approach can facilitate patients being seen in locations nearby, such as hotels, rather than in the home, in order to maintain privacy and still make research more accessible.

Also discussed was the lack of access to WiFi or a good data plan for some participants, which could create a challenge for study-based patient apps and telehealth visits. This can be overcome by the sponsor provisioning devices and data plans, which should be incorporated into the planning stage of a study, based on up front conversations with patients and site staff. The pandemic has shown that such an approach can be highly beneficial to patient oversight and engagement, with one physician stating:



Dr. John Otasowie
Physician Focus Group Participant

John Otasowie, MD, is the Regional Divisional Head for Child, Youth and Young Adult (CYYA) Psychiatry with the Fraser Health Authority in British Columbia, Canada. He works as a consultant child and adolescent physiatrist, providing support and care for young people admitted to the Child and Adolescent Psychiatric Stabilization Unit and the Regional Youth Concurrent Disorder and Eating Disorders Programs at Surrey Memorial Hospital.



Dr. Kathleen Young
Physician Focus Group Participant

Kathleen Young, MD, treats children, adolescents and adults for medication management, psychotherapy and forensic evaluation. In the community, Dr. Young volunteers with the New York Junior League, where she has most recently been involved with leadership training and diversity, equity and inclusion initiatives. She currently serves on the Management Council in the role of Secretary.

NEXT CHAPTER
Institutional and structural racism

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Institutional and structural racism

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During physician focus groups, several practical considerations were raised that were not highlighted when learning from patients. There was a general sense that neither minority patients nor minority physicians receive the same opportunities for research involvement as their white counterparts. Both societal and institutional changes will be required to level the playing field in this regard:

Dr. Valerie Stone
Physician Focus Group Participant

Valerie Stone, MD, MHP, is Vice-Chair for diversity, equity, and inclusion of the Department of Medicine at Brigham and Women's Hospital (BWH). Dr. Stone is an academic general internist as well as an infectious disease specialist and is a Professor of Medicine at Harvard Medical School.

This was also highlighted during the Patient Advisory Council as another element that can lead to mistrust:

»»»»»»»»»»»»»»

Alfred Samuels
Patient Advisory Council Member

Alfred Samuels is a patient advocate, speaker and author. He was diagnosed with advanced metastatic prostate cancer in 2012 and just passed eight years as a survivor of the disease. Alfred also serves as an ambassador for Cancer Research UK.

Physicians also highlighted a perceived lack of representation within the pharmaceutical industry as being a barrier to achieving equity in clinical research access. With the industry focused on diversity, the situation continues to evolve with the extension of inclusive practices to ensure greater representation:

»»»»»»»»»»»»»»

Dr. Shelly McDonald-Pinkett
Physician Focus Group Participant

Shelly McDonald-Pinkett, MD, FACP, CPHQ, is Chief Medical Officer of Howard University Hospital. She is also an Associate Professor of Medicine and Howard University College of Medicine and serves as Interim Chair of the Department of Internal Medicine. In addition, Dr. McDonald-Pinkett is Program Director for the International Medicine Service Learning Program, MediNova board member, District sof Columbia committees member, and, most recently, was selected to serve on the Washington Regional Transplant Community Board of Directors.

KEY TAKEAWAY

Proactively engaging with existing sites to support them in accessing a diversity of communities and selecting and partnering with new sites that work with patients from underrepresented backgrounds is an important step to more inclusive clinical research.

NEXT CHAPTER
Increasing Research Involvement

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Increasing Research Involvement

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For those physicians not working in hospitals where clinical research is the norm, knowing how to get involved was also cited as a key challenge. To overcome this, long-term mentorship, adequate financial compensation, and guidance and training provided early in a career path by those with experience was cited as an important way to address this barrier. In turn, this could successfully increase the rates of clinical research involvement for physicians from all backgrounds:

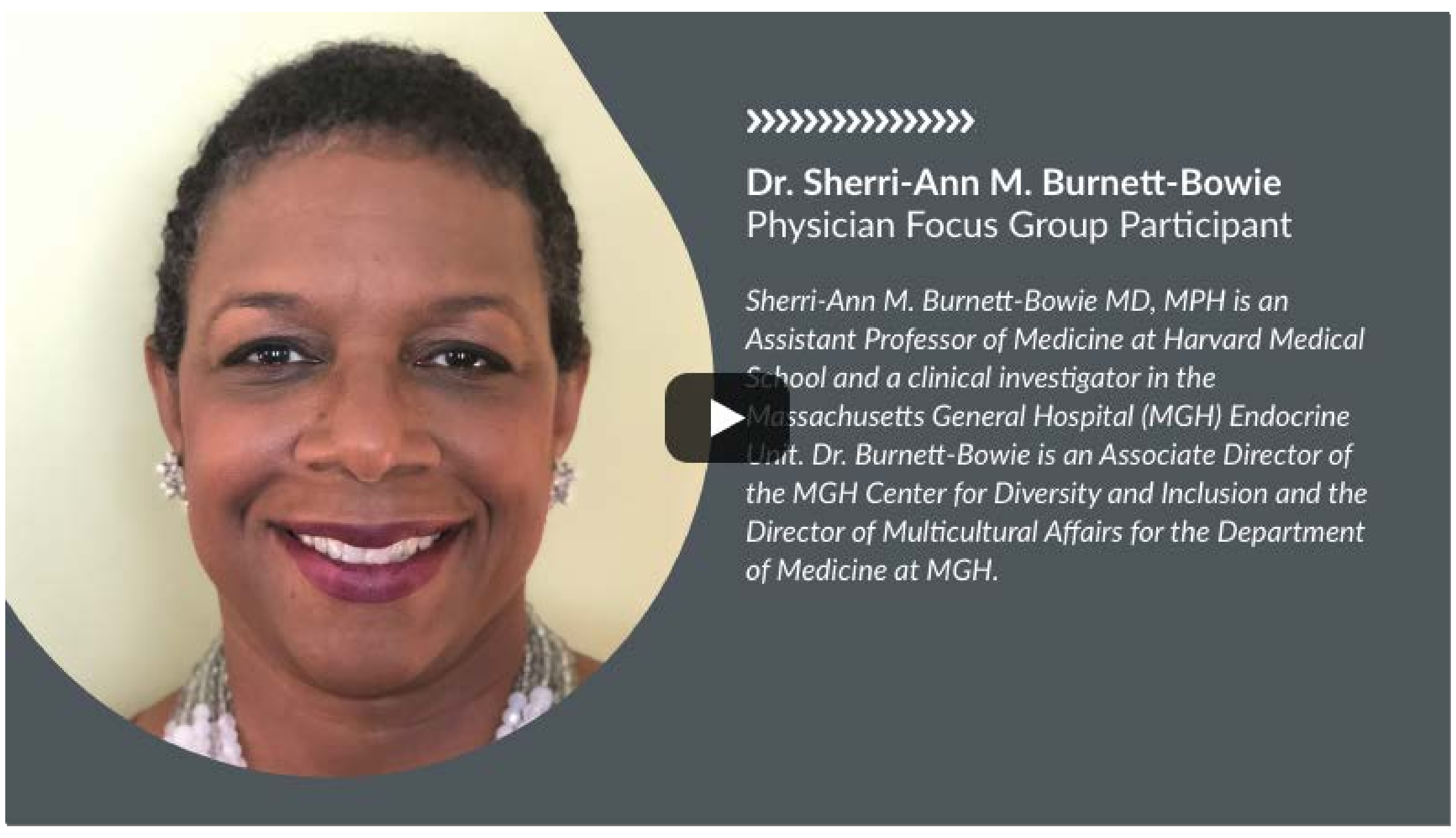
> “It’s much more than training and education. There must be an offer of employment and sponsorship…
>
> **Dr. Shelly McDonald Pinkett, Physician Focus Group Participant**

Also important is hospital infrastructure, as support and funding that includes assistance from the pharmaceutical industry could greatly help with the undertaking of clinical research on an ongoing basis and lead to success:

Dr. Valerie Stone
Physician Focus Group Participant

Valerie Stone, MD, MHP, is Vice-Chair for diversity, equity, and inclusion of the Department of Medicine of Brigham and Women’s Hospital (BWH). Dr. Stone is an academic general internist as well as an infectious disease specialist and is a Professor of Medicine at Harvard Medical School.

It is well known that involvement in clinical research is low across the entire healthcare profession. A lack of training on the topic during medical school and lack of exposure within hospitals are likely the primary reasons for this. Physician participants agreed that these barriers exist but that being paid less to lead research than to see patients was also a deterrent. This underscores the need to educate about the importance of clinical trials and medical research while removing barriers related to earnings, such as accessible grants.



Dr. Sherri-Ann M. Burnett-Bowie
Physician Focus Group Participant

Sherri-Ann M. Burnett-Bowie MD, MPH is an Assistant Professor of Medicine at Harvard Medical School and a clinical investigator in the Massachusetts General Hospital (MGH) Endocrine Unit. Dr. Burnett-Bowie is an Associate Director of the MGH Center for Diversity and Inclusion and the Director of Multicultural Affairs for the Department of Medicine at MGH.

Training existing sites on new approaches for accessing a diversity of communities as well as enhancing the diversity of sites by selecting and partnering with new sites and physicians from different racial and ethnic backgrounds would be worthwhile. Approaching new sites outside of the large inner-city teaching hospitals will also be important in order to reach physicians who are working in community hospitals. In particular, sites that have already built trust with communities by working with them and getting to know them better would greatly improve diversity in clinical research.

> “I love the idea of healthcare workers being involved in the community, who are able to speak to specific trials and explain to patients in their own language what it really means to participate and the potential benefit it offers to the community.
>
> **Dr. Shelly McDonald-Pinkett, Physician Focus Group**

NEXT CHAPTER
Trial Feasibility

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Trial Feasibility

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During discussions, it was noted that the pharmaceutical industry tends to work with a similar pool of sites with a proven track record. With an ongoing lack of patient representation, particularly from the Black community, the industry must be more deliberate with their site-selection process to enhance trial diversity:

> “Pharma companies need to make sure they update their feasibility questionnaires so that sites can be proud of the fact that they have a diverse community culture to bring these types of patients into the studies.
>
> **Dr. Fabian Sandoval, Physician Focus Group Participant**

Physicians also provided feedback that the pharmaceutical industry has historically been perceived as reluctant to ask questions outright about diversity in patient populations or staff for fear of causing offense. Without resolution, this could limit progress toward proactively inclusive practices that improve representation within clinical research.

Wanda McClain
Physician Focus Group Participant

Wanda McClain is the Former Vice-President of Community Health and Health Equity at Brigham and Women's Hospital (BWH) in Boston, MA. She leads the Center for Community Health and Health Equity at the Brigham, its two licensed community health centers and its relationships with affiliated health centers in Boston. She strives to fulfill the Brigham's strategic commitments to community health, health equity and high-quality patient- and family-centered care.

NEXT CHAPTER
Conclusion & Acknowledgements

Conclusion

Research participants have stated clearly that trust-building and community engagement are needed to engage and recruit participants from communities that have historically been underrepresented in clinical research. Long-term openness, transparency, support and the common goal of improving the health of everyone are required to enable meaningful change.

> “Inclusion of diverse participants and investigators is central to achieving excellence in research. Now more than ever, we need to focus on achieving excellence through inclusion.
>
> **Dr. Sherri-Ann Burnett-Bowie, Physician Focus Group Participant**

To summarize, overcoming racial, ethnic and cultural disparities in the clinical-research industry will depend on efforts that engage on multiple fronts, including:

- Building trust through sustained patient and trusted community-advocate engagement, and improved medical-staff diversity
- Providing patients and physicians with education and opportunities to join trials
- Industry stakeholders addressing their own staff diversity, site engagement and feasibility practices to positively alter their approach to optimizing diversity in clinical research
- Explaining the nature of a potential trial with simple language, using relevant channels of communications and engaging trusted advocates who relate to respective cultural and socioeconomic backgrounds
- Exercising awareness of what is being asked of communities to take part in research
- Reducing or eliminating the logistical challenges created by taking part in research
- Investment in training new and future researchers and supporting their advancement to leadership roles in academic-and industry-based clinical research
- Investment in building research capacity in community-based research sites within diverse communities

If clinical trials are to be effective measures in informing us about the promise of new treatments, we must also then be committed to doing what is required to ensure a demographically representative population in these clinical trials. Even though these nuanced issues are often challenging and complex, through collaboration and outreach, many barriers to clinical-trial diversity can be overcome.

> “Now, with a broadened perspective and greater understanding of the critical areas to address, we invite our industry colleagues to reflect together on diversity practices and identify opportunities to improve engagement with sites and patients from different racial and ethnic communities. By putting patients first, we have a clear opportunity to enhance research access for patients around the world.
>
> **Jamie Macdonald, Parexel CEO**

Acknowledgements

This report incorporates learnings and insights from data derived from a series of surveys and patient/physician focus groups, which gathered insights concerning various topics on clinical trial diversity. We thank all participants for their time, openness and expertise. While many were anonymous, we are pleased to acknowledge those who were not, namely:

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