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Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

INvestigation of Co-occurring conditions across the Lifespan to Understand Down syndrome (INCLUDE) Project

Diversity, Equity, Inclusion, and Accessibility (DEIA) Webinar Series

Value of Diverse Perspectives in Down Syndrome (DS) Research

June 26, 2023

Background

This webinar was designed to explore the importance of engaging diverse communities in research and to learn how to apply successes from other programs to DS research activities. Themes included engaging the DS community in research, expanding the diversity of DS research participants, and increasing diversity among DS researchers and trainees.

Welcome

Sujata Bardhan, M.S., Ph.D., Program Director, NICHD

Linda Garcia, Communications and Outreach coordinator, INCLUDE Project and DS-Connect®: The Down Syndrome Registry, NICHD

Marjorie Vandy, Extramural Staff Assistant, NICHD

Dr. Bardhan, Ms. Garcia, and Ms. Vandy welcomed attendees from the United States, Latin America, Central America, and Africa to the [INCLUDE Project](#)'s DEIA Seminar Series inaugural webinar. The topic was the value of diverse perspectives in DS research. In both English and Spanish, the moderators provided instructions for using the webinar platform's Spanish interpretation feature, turning on closed captioning, and asking questions during the facilitated discussion period. American Sign Language interpreters provided live interpretation of all meeting content.

Engaging Underrepresented Communities in Biomedical Research through the *All of Us* Research Program

Karriem Watson, D.H.Sc., M.S., M.P.H., Chief Engagement Officer, All of Us Research Program

Dr. Watson leads the *All of Us* Research Program's Division of Engagement and Outreach, overseeing the program's efforts to foster relationships with participants, community partners, researchers, and providers across the United States. His focus is on engaging people and populations who have been left out of medical research in the past and inviting them to help drive new biomedical discoveries.

Dr. Watson described the *All of Us* Research Program and its efforts to engage underrepresented communities and researchers in biomedical research, discussed how *All of Us* participant data reflects intersectionality within underrepresented communities, and highlighted what *All of Us* has achieved with its Researcher Workbench and data.

A Precision Medicine Initiative

All of Us uses its resources to engage populations that have been historically underrepresented in biomedical research (UBR). The program has been intentional in addressing DEIA, and it emphasizes the intersectionality of research across the life span for UBR (and all) participants. *All of Us* has also been successful in achieving a diverse researcher network by collecting a large amount of data from diverse communities.

In 2015, the [Precision Medicine Initiative Working Group](#) of the Advisory Committee to the Director submitted its [final report](#), which provided the framework for establishing the *All of Us* Research Program. *All of Us* is inviting one million or more participants with diverse backgrounds from across the United States to enroll in the program and help build one of the largest, richest, and most diverse health datasets in history. Using the data collected, researchers will study how biology, lifestyle, and environment affect health and use that data to find ways to treat and prevent disease. The program's overall goal is to accelerate health research and medical breakthroughs by enabling individualized prevention, treatment, and care for all of us. A one-size-fits-all approach cannot properly address health disparities research.

The data types that *All of Us* is collecting include survey responses, electronic health records, physical measurements, Fitbit information, biospecimens (blood, urine, saliva), and genomics (whole genome sequences, structural variants, genotyping arrays, long-read sequences). Collecting many data types creates a “one-stop shop” for researchers. As of April 2023, the program's Researcher Workbench contained the largest set of whole genome sequences that are now widely available for research.

Genomic data from other studies is largely (78% or more) from European populations, with the remaining 2% from African descent, less than 1% from Hispanic or Latino descent, and less than 0.5% from other minorities. This lack of diversity leads to a lack of generalizability for any findings to apply to citizens across the United States or the world. Importantly, among the more than 651,000 participants enrolled in *All of Us*, about 51.5% self-identify as having White (European) ancestry; 17.9% self-identify as Black, African American, or African; 16% self-identify as Hispanic, Latino, or Spanish; 3.1% self-identify as Asian; and 6.8% self-identify as having more than one racial background. Other race categories include Middle Eastern or North African and Native Hawaiian/Pacific Islander. Approximately 80% of all participants fall into at least one UBR category.

The Engagement Ecosystem

The inclusion and enrollment of diverse populations has come through intentional community engagement and the building of a large, relationship-based engagement ecosystem. The *All of Us* Division of Engagement and Outreach prioritizes outreach and engagement to communities (including Tribal Nations), participants, and researchers, and it works to ensure program visibility. Beyond building relationships, engagement strategies include advancing and applying

the science of engagement, retaining participants, equipping researchers, and creating a return-of-value cycle.

All of Us currently has 14 national engagement awardee organizations representing historically UBR populations: the American Association on Health and Disability (AAHD), Baylor College of Medicine, the Asian Health Coalition, Delta Research and Education Foundation, FiftyForward, the National Alliance for Hispanic Health, Pyxis Partners, the University of Utah, the National Baptist Convention USA, the Network of the National Library of Medicine, RTI International, Stanford University PRIDEnet, the University of Florida, and Northwell Health.

All of Us holds listening sessions to learn what is important to diverse communities for inclusion and engagement in research and to learn about barriers to participation. One barrier is a lack of trust, which can only be overcome through relationship building. Certain communities have justified and understandable medical mistrust; for example, the program held a town hall in Tuskegee, Alabama, to address the historical medical mistrust that exists there due to the United States Public Health Service study that studied untreated syphilis in African American men. Other communities have a lack of the trust due to access and awareness. Conversations led by people like Veronica Robbins, the great-granddaughter of Henrietta Lacks, help potential participants tell *All of Us* how to conduct a more ethical and inclusive study.

Community engagement includes outreach and awareness to individuals, families, caregivers, and advocacy organizations. Education and access activities promote understanding around participating in research. Engaging, enrolling, and retaining participants makes them fully informed. Treating participants as partners elevates their voices, expertise, and experience as collaborators. Knowledge gained through research must be mobilized beyond publication and conferences; an engaged community can help researchers understand and use the data and then ask informed health questions.

Examples of effective community engagement for *All of Us* include the Asian Health Coalition reaching more than 158,000 participants across the nation by conducting 391 virtual and in-person events with more than 22 partners; the National Alliance for Hispanic Health scheduling the program's mobile engagement asset to come to the organization's coordinated events, resulting in almost 2,000 quality conversations and the enrollment of more than 200 participants; and Pyxis Partners creating a network of 151 partners across the United States, including the National Rural Health Association, to help create access to clinical trials. The program asks its 35 participant ambassadors and 10 participant partners to serve on steering committees, executive committees, and advisory panels. With Northwell Health, *All of Us* conducts "community sandbox workshops" to promote the use of its data. *People Magazine* recently featured Michelle, a participant ambassador, to highlight her journey and learn why she said it was important for her to participate in the program. Another participant ambassador joined all the program's research partners at a national conference to talk about the importance of participant voices in the program.

Intersectionality in Biomedical Research

In collecting its data, *All of Us* prioritizes the intersectionality between biology, environment, lifestyle, and social determinants of health. For example, researchers can analyze information from participants with annual incomes of less than \$10,000 per year (13.6%), who have a

highest grade level achieved of ninth through eleventh grade (5.8%), who are not covered by health insurance (6.5%), and who have been worried or concerned about not having a place to live within the last six months (16.3%). Connecting social information with genetic, biological, and environmental factors may allow researchers to better understand intersectionality across the life course and ask research questions that address health disparities. *All of Us* data could someday be used to build better tools for detecting health conditions, to determine how environment, lifestyle, and genes impact health, and to identify who is more likely to develop a disease. The *All of Us* cohort also includes UBR participants who identify into sexual and gender minority (SGM) groups (about 10%), report living with a disability (16.1%), and live in a rural community (7.1%).

One of the program's community partners, AAHD, invites participants living with disabilities to contribute to research to advance individualized treatment and care for all. With the vision statement of "Nothing About Us Without Us," AAHD has been instrumental helping *All of Us* develop disability definitions and metrics and brainstorm ways to include more populations, including people with intellectual disabilities. Stanford University PRIDENet has been instrumental in helping *All of Us* engage with the SGM community and has provided education to ensure that researchers understand the correct language and cultural values to use when engaging with this population.

There are multiple ways for INCLUDE and *All of Us* to work together to develop community awareness of clinical trials and appropriate engagement materials for assessing health outcomes, quality of life, cognitive functioning, behavior, and mental health (conditions that are important to all communities).

To learn more about the program, visit [Allofus.nih.gov](https://allofus.nih.gov). To find out how to become more involved in the research program as a partner or researcher, visit researchallofus.org/explore or contact Dr. Watson at karriem.watson@nih.gov.

Diversity in Clinical Trial Research: Barriers and Solutions for Engaging the Latino Community

Amelie G. Ramirez, Dr.P.H., M.P.H., Professor and Chair, Department of Population Health Sciences; Director, Institute for Health Promotion Research (IHPR), University of Texas (UT) Health San Antonio

As director of the IHPR, chair of the Department of Population Health Sciences, and associate director of cancer outreach and engagement at the Mays Cancer Center, all at UT Health San Antonio, Dr. Ramirez investigates causes and solutions to cancer and chronic disease disparities to improve Latino health in San Antonio, South Texas, and the nation.

The Latino Community

Dr. Ramirez said that the Latino community has grown significantly in the United States. Census data show a 23% increase in the Hispanic/Latino population from 2010 to 2020, to 62.1 million residents, which represents 19% of the entire U.S. population. The terms that are used to describe this population are sometimes controversial. *Hispanic* is a government term. Dr. Ramirez said that people from Latin America prefer to be called *Latinos*. There are also differences between the east and west coasts in how people refer to their Spanish descent. The

highest concentrations of Latinos (44%) are in Texas and California, but Hispanic/Latino populations are growing in every state. Even the northern states are seeing increases in Hispanic populations (North Dakota 135%, South Dakota 74%, Montana 72%). The Latino community's major challenges include lower levels of education and income, higher rates of poverty, and poor access to healthcare.

Latino Clinical Trial Participation

Latino community leaders have begun focusing on clinical trial enrollment because it is important to have medications that work for all population groups. Underrepresentation of diverse participants in clinical trials has led to extremely limited information about medication use in most racial and ethnic groups. Although Latinos make up 19% of the U.S. population, they represent only 4% of the enrollment in some FDA clinical trials and fewer than 10% of some NIH trials (less in genomics research).

Barriers to clinical trial participation by Latinos include a lack of awareness about why trials are important and why Latino participation is important, less knowledge about diseases and treatment options (i.e., that a trial is a treatment option), cultural or language and literacy issues when information is not available at an understandable reading level with representative pictures in printed materials, and the cost to participate in a clinical trial in the setting of the lowest rates of insurance coverage (e.g., being unable to pay for basic laboratory tests that are required to determine eligibility for a clinical trial). The cost to travel to trial centers when most trials are not available in rural areas or smaller cities is prohibitive, as is the limited general availability of good transportation.

There are many implications of the underrepresentation of Latinos in clinical trials. Cancer is on the rise in the Latino community, the population is aging, and there are no treatments tailored for this group. Some of the cancers found in the Latino population are understudied and not commonly seen in the general population (e.g., liver, stomach, gallbladder, and cervical cancer). Cancer has become the leading cause of death for Latinos, but the reason is not well understood.

Overcoming Barriers to Participation in Clinical Trials

UT's medical school and cancer center are working to help overcome barriers to participation in clinical trials. They are emphasizing building trust between patients and physicians, fostering the understanding and belief that joining a clinical trial both helps future cancer patients (future generations) and offers possible benefits to participants, presenting information in an easy-to-use format to increase knowledge about clinical trials, and encouraging family support. Because individual patients and their supportive family members are all included in the patient's decision making, the entire family is engaged.

The UT Mays Cancer Center completed a self-evaluation, asking, "What does clinical trial participation look like here?" Although the center provides care for 38 counties in south Texas with a 60% Hispanic or Latino population, this group was underrepresented in clinical trial enrollment. The center then conducted focus group interviews with patients and providers to identify obstacles for enrolling Latinos in trials. The center expanded educational efforts in the community with patients and providers and asked providers whether they were doing their best to ensure that the clinical trial inclusion criteria were applicable to the local population.

The outcome was the development of a system-wide, mandatory minority accrual plan for all clinical trials. Now, any investigator who opens a clinical trial at the cancer center must write a minority accrual plan for enrolling as many participants as possible from the service area and must use a checklist to develop tools for the recruitment of minorities. Program coordinators translate informed consent forms and informational videos and help implement the many ways listed on the checklist to encourage clinical trial participation. These initial efforts produced a modest increase in Latino clinical trial participation, from 42% to 49%.

With support from the Susan G. Komen Foundation, the cancer center created [Choices](#), an intervention designed to empower Latinas to make informed decisions about participating in breast cancer clinical trials. It used online videos, booklets, and patient navigations tools to enhance Latina knowledge, attitudes, and skills; increase self-efficacy (i.e., seeing others like themselves making positive decisions about whether they should participate in a trial); and encourage discussion of clinical trials as a treatment option (with their doctor and with their family). Materials were provided to patients diagnosed with breast cancer who were eligible for the study but had not yet consulted with their doctors or participated in a clinical trial. Education about the different phases of trials was also provided. The Choices intervention was effective in improving perceived understanding of clinical trials and increasing consideration of participating in clinical trials as a treatment option.

Dr. Ramirez shared the following lessons learned from the cancer center's self-evaluation and [Choices](#) intervention:

- Raising awareness alone does not improve participation; other barriers must be addressed.
- Barriers to participation in clinical trials are complex and multifaceted (health system, provider, patient).
- Clinical trial investigators must provide comprehensive patient information and work alongside providers and their patients.
- Patient navigators who look like patients can be used to help answer questions (some patients feel more at ease asking the navigator versus the doctor) and then follow up to further explain the options the provider gives to the patient.
- Computer-based videos can increase patient's knowledge and understanding of clinical trials and promote participation.

Salud America!

The UT cancer center has developed a large advocacy network called "[Salud America!](#)" It is a national health equity digital communications network with more than 500,000 Latino followers on its website, social media, and email platforms. Salud America! began as a childhood obesity prevention program, but it has been expanded to identify social determinants of health affecting the Latino community. It provides culturally relevant infographics and short videos on different topics and issues of importance to the community. A grant from Genentech was used to create a program focused on clinical trial enrollment to expand the inclusiveness of clinical trial recruitment. The cancer center reaches out to advocacy network organizations and clinical partners to promote health equity and advance clinical trials for both cancer and Alzheimer's disease (which also affects Latino communities). Because

Latinos are among the largest users of social media, the program has been successful using Facebook and webinars to reach its target audience.

To improve clinical trial enrollment, the UT cancer center uses the Salud America! model to develop bilingual, bicultural clinical trial educational resources. Latinos who have participated in a clinical trial are interviewed and asked about whether clinical trial participation is important and what kind of a difference participating has made in their life. Latino physicians are interviewed about their experiences and feelings on clinical trials. Beyond participation in clinical trials, the program promotes the need for biospecimen donation to speed research discoveries. The program also promotes NIH websites with clinical trial information and open trials available locally.

Furthermore, to ensure that providers do not make decisions for Latino patients, the UT cancer center is working to increase health care workers' knowledge of implicit bias. An educational program for providers, the "[Find If You Have Implicit Bias](#)" action pack, helps identify bias that might prevent people who are truly eligible from participating in a clinical trial. The action pack, which has been downloaded more than 720 times, helps providers who are carrying bias learn how to change their actions and become more open to inclusiveness.

Best Practices and Recommendations

Dr. Ramirez listed the following as best practices and recommendations:

- Use educational videos that are culturally tailored, clear, and easy to understand. The best videos include a strong personal narrative of why it was important for a patient to participate in a clinical trial.
- Employ patient navigators who are available via phone or text messaging. Patients diagnosed with cancer or other life-threatening diseases receive so much information that it is hard to absorb it all and know what to do. Having someone who is available during flexible times, who can visit the home, and who can interact with family members during the consent process and study visits is important.
- Use social media platforms to promote clinical trials, dispel misconceptions, and engage community members and potential participants. During the COVID-19 pandemic, Salud America! became one of the Latino community's go-to sources for health information.
- Create collaborative conversations. To push the science of cancer, the UT cancer center has hosted a biennial conference since 2018 to invite national and international representatives to share what they are doing to promote cancer research within the Latino community. Everyone is invited to attend [the next conference](#), which is scheduled for February 21–23, 2024.

Recommendation for INCLUDE

There is a need to better understand cancer risk and resiliency in people with DS. Although there is a 10- to 20-fold increase of certain types of cancer (e.g., acute lymphoblastic leukemia, acute myeloid leukemia) in children with DS compared with neurotypical children, children with DS appear to be protected from developing solid tumors (e.g., tumors of the breast, lung, kidney, brain, and prostate). There are opportunities for new research in several areas of cancer. Dr. Ramirez welcomed partners for creating a more inclusive population in cancer research.

Participant Perspectives in DS Research

Leesha Thrower, Ph.D., Professor and Chair, Department of Communications and Theatre Arts, Cincinnati State Technical and Community College

Jaia Thrower, Dr. Thrower's 11-year-old daughter, who has DS

Dr. Thrower helps lead the DS Association of Greater Cincinnati and the African American Family Network's DEIA committee. Ms. Thrower is a rising seventh grader and swimmer. In school, her favorite subject is math. The webinar moderators used a Q&A format with Dr. Thrower and Jaia to learn their perspectives on DS research.

Q: Jaia, can you tell us a little bit about yourself and your experiences participating in DS research? Jaia: My name is Jaia Thrower, and I will be 12 years old on Friday. I will be in seventh grade at Princeton Community Middle School. I am on a swim team called the Sharks, and I swam at the Special Olympics. I like to go to King's Island [an amusement park] and go on some rides. I like to dance. I participated in a research study two years ago. Another study is coming up soon, but it is a little boring. I wish my friends were there.

Q: What kind of support or accommodations do you think would be helpful for you to participate in DS research? Jaia: I would like to take breaks when there are too many questions. I like to play games. Dr. Thrower: That is a good point—breaks are needed if there are a lot of questions. On the topic of time, I understand that researchers want to get home because they have a life outside of work, but it is hard to do research in the middle of the school day. Jaia gets out of school at 3:00 p.m., so I may need to pick her up early from school, and that becomes an inconvenience. Having child care available would be beneficial, especially for people with other children, because parents are expected to fill out surveys while their child is participating in research.

Q: Are there specific areas or topics within research that you find interesting, fun, or important? Jaia: I want to drive like my brothers, so that would be good to learn. Dr. Thrower: Yes, Jaia is interested in driving. Jaia: One of my brothers is 22, and he wants to play football for the Miami Dolphins. Dr. Thrower: From a parental perspective, I am interested in research that will help Jaia live her best life and learn to be as independent as possible. Fortunately, she has been relatively healthy. I am particularly interested in research dealing with technology; for instance, Alexa was helpful when Jaia had surgery, because Jaia could call me on Alexa. If I had to run to the grocery store, Jaia could call me, and I would answer it on my phone or voice to text. It would be nice if when they made that technology, they had people with DS or other speech impediments participate so Alexa could learn their voices. If that technology was available, it would help them live extraordinary lives ... they could use technology to buy groceries or complete banking tasks. I am also interested in obesity research within the DS community. I am convinced that there is a gene that does not tell them when they are full. I do not know if that is the cause, but I would love to know if it is. We are heading into puberty, so that is always interesting. Finally, anything that would improve comprehension would be very beneficial.

Q: Can you share any past experiences you have had with research studies? Jaia: The first study was in Cincinnati when I was 10 years old. I worked with Shequanna, and she was nice. She gave me snacks, and she also gave me a hair scrunchy. Sometimes it was going to take too

long. It was hard to stay awake. Dr. Thrower: Jaia's first research experience was at Children's Hospital. The researcher was wonderful. It was hard for Jaia to stay awake, because at that time she was not sleeping well and would wake up in the middle of the night. So by the time we got to the appointment, she was extremely tired. The researchers had to figure out the best ways to keep her engaged. Jaia: Yes, and I had Pinky with me, and I got to go to my big brother's basketball game. Dr. Thrower: Pinky is her best friend [Pinky was pictured on the slide alongside Jaia].

Q. Are there any challenges or barriers that might affect your ability to participate in research? Jaia: Yes, I can't miss school, swimming, or camp. Dr. Thrower: Jaia did miss summer camp today to attend this webinar. She was willing to miss it today. So that would be something that would affect her participation. As a parent of multiple children and working full time, it is hard to commit to participate in longitudinal studies. I have a doctorate degree, so I understand the importance of longitudinal studies. Committing to participate is fine, but then life happens and the schedule that seemed clear is no longer open. It is a challenge to figure out how to manage everything. The other challenge—which is not an issue for me, because I only teach a few days per week as a professor—is the issue of time. Although I can rearrange my schedule, not everyone has a flexible schedule. The time of day that studies are conducted is a barrier for most people. Most people that we know, our friends, would have been unable to complete the research that Jaia was in, because participating would have required them to leave work to go across town. It would have been too much.

Q. How would you like your participation in research to have a meaningful impact on the DS community? Jaia: I hope it helps people with DS like me and my friends. My mom promised me a trip to Target today. Dr. Thrower: Yes, I promised her a trip to Target and McDonalds today for helping with the webinar. Jaia: That picture is of me at my very first school dance.

Q. How do you feel about your child's participation in DS research, and what expectations or concerns do you have for her participation? Dr. Thrower: Research is essential, and the right research takes us to the next level and helps us progress, so I understand how vital it is. The goal is for Jaia to live an extraordinary life. I also understand the importance of diverse voices, as mentioned by the two previous presenters. Diversity and diverse perspectives are not only differences in race; cognitive ability and socioeconomic status are other types of diversity. My goal as a parent is for Jaia to live her best life, but the goal is not only for Jaia. In this community, we have made lifelong friends who would go out of their way for us, and we would do the same for them. Research should allow the entire community to progress. I have several concerns with research. One is that theory and practice are different. You can research DS and understand a checklist of what DS is and develop some ways to help people with DS, but that is different from being a part of the community. The reason I raise this concern is because when it comes to a research design or research questions, being a part of the community will help researchers understand what the community wants, what the community thinks is vital, and the best way to design the studies. After researchers get to know the community, they may come up with a different study design. Sometimes the questions that we are asked, like being compared against neurotypical children instead of comparing this community to itself, are the wrong questions and are creating a deficit model. It is hard to participate in research knowing that we are being compared to a group that is not like us. I would like to see research “for us, with us” as the norm for people with DS, the central participants in the research. It is also

important to think creatively about research designs that make sense. For example, Jaia was talking about research with Shequanna. During that study, Jaia was getting distracted. Jaia was tired but noticed that Shequanna had a pretty scrunchie in her hair. Shequanna said, “Next time I will bring you a scrunchie,” and she did. She remembered, and she brought it. Shequanna was open to accommodating us with breaks and snacks; she was flexible and made accommodations that fit within the confines of the study. My concerns are that sometimes researchers are so stringent that they will not make accommodations.

Q: How can NIH researchers encourage more families from your community to take part in research studies? Dr. Thrower: I always tell people about the best research study in which I participated. It included all the items listed on this slide: focus groups, bridge, no political agenda, compensation, flexible time and practice, child care, and connection to the research. My friend, who is a researcher, said she wanted to do research about DS and include the African American community. She asked me, “What can we do?” I went back to my group as a bridge and asked if they were interested in participating together. The researchers came to us, to our DS association office, in the evening, to conduct a focus group. Families were there with others with whom they already knew or felt comfortable. There was a separate room in the same building for child care so that parents could participate. The children with DS were in another room in the same building. The researchers provided dinner for the families and some compensation—a gift card given right away; we did not have to wait around for it. Every element of this wonderful research project was flexible and took the families’ needs into consideration. I absolutely loved it. There was no political agenda—e.g., researchers come to our community only to try to get us to participate in research, but we never see them again. Anna Esbensen, Ph.D., from Cincinnati Children’s Hospital, does a great job engaging with our community and being a part of the community. If she needs participants for research, families are willing to help because they know her. She supports our community outside of needing research subjects. Research is often abstract and cumbersome to read. For research on cognition, comprehension, or behavior, if researchers would come back after a study was complete with one page that I could give to Jaia’s intervention specialist and say, “Here is how you can help Jaia,” or some notes on what to do at home, such as three things based on our work with Jaia that you can do to help her comprehension at home, then I would feel more connected to the research.

Closing Comments

Melissa Parisi, M.D., Ph.D., Chief, Intellectual and Developmental Disabilities Branch, NICHD

Dr. Parisi thanked the speakers and provided closing comments to summarize the webinar content. She said that Dr. Watson and the *All of Us* Research Program are moving away from the “one-size-fits-all” mentality for research to promote diversity and inclusion. *All of Us* is ensuring that research participants come from UBR populations. Dr. Watson emphasized the importance of trust and relationship building to develop the alliances and partnerships that ensure that populations feel a part of the research and included. He also talked about intersectionality, the importance of participant ambassadors, and how not to pigeonhole people into only one category or another. The motto “nothing about us without us” is something that all researchers should keep in mind when creating diverse research programs.

Dr. Ramirez and UT Health San Antonio are trying to increase participation of the Latino population in research, especially research related to cancer clinical trials. Although the Latino population represents 19% of the U.S. population, only 4% of FDA drug trials and 10% of National Cancer Institute–sponsored clinical trials include people who are Latino, indicating that there are many barriers to participation. Dr. Ramirez shared important strategies for boosting participation in clinical studies and the importance of going beyond raising awareness to engage and educate patients. Researchers must engage with and teach participants how to make informed health care choices, using online resources, videos, booklets, patient navigators, a variety of multidisciplinary social media, and other approaches.

Dr. Thrower and her daughter, Jaia, shared their perspectives on participating in research. There is nothing better than hearing straight from the research participants. Jaia’s comments about taking breaks, including friends, and accommodating work and school schedules were well received. Dr. Thrower’s perspectives as both a mom and a researcher are incredibly insightful. What is vital in research needs to come from the community. Researchers need to acknowledge and respect families’ busy lives and schedules and do everything possible to ensure that families can participate in research.

The words of wisdom from participants, families, investigators, and members of the DS community will guide researchers embarking upon the next five years of the INCLUDE research program. INCLUDE will continue to emphasize DEIA, and continued input is welcome.

Discussion

Sujata Bardhan, M.S., Ph.D., NICHD Program Director

Linda Garcia, Communications and Outreach coordinator, INCLUDE Project DS-Connect®: The Down Syndrome Registry, NICHD

Q: How many participants with DS are enrolled in the *All of Us* Research Program? An *All of Us* researcher: About 40. Dr. Bardhan: NICHD has a registry for people with DS called DS-Connect, the DS Registry; there may be ways for NICHD to partner with *All of Us* to invite the 5,000 or more participants in the DS Registry to join *All of Us*.

Q: You mentioned being concerned about obesity. Is obesity in the DS community different from obesity outside of the community? Dr. Thrower: It feels different to me, but it would be wonderful to know whether it is similar. Other parents and I often wonder whether there is something that prevents people with DS from knowing that they are full. It may be related to the fact that many people with DS have mobility issues or low muscle tone. My daughter has had a lot of issues, including surgery on her foot in March. She will need surgery on the other foot next year. These issues prevent her from being as active and walking as long. This is a research topic that the DS community would appreciate. Dr. Ramirez: I would like to add that obesity is a critical issue for many children. For example, 30% of Hispanic children between the ages of 2 and 19 are overweight or obese. This is something to address as a national issue. A DS researcher: We are aware of the need for more research on obesity and appetite control in people with DS. There are many large cohort studies taking body mass index measurements and tracking the overweight phenotype to other characteristics (e.g., co-occurring conditions, physiology). I am fascinated by the notion of a loss of appetite control in DS, which could be tied to our understanding of sleep disturbances and obstructive sleep apnea in people with DS.

The mechanisms that help control appetite, such as the hormone leptin, become dysregulated with loss of sleep. Normalizing sleep during the night may help with appetite control during the day. I look forward to sharing more of this research with you and the rest of the community in the years ahead.

Q: Dr. Watson, I was intrigued to see your mobile engagement asset. What does it entail, and what resources are part of this asset? Dr. Watson: The Montage Marketing Group helped develop our mobile engagement assets, and AAHD helps make our mobile engagement asset accessible. The assets allow *All of Us* to go into communities and meet families (especially in rural communities). Unfortunately, most research studies are conducted in academic medical centers, leaving out geographic locations where many health disparities are found. The mobile engagement asset is a large van that helps the program with enrollment, building awareness of the importance of genomic studies, and learning about the consent process and data collection. I can provide the list of where the mobile engagement asset will be going throughout the country.

Q: Dr. Ramirez, you mentioned that you conducted several focus groups to understand barriers to participating in clinical trials. Could you elaborate about potential reasons why the Latino community has been reluctant to participate in the DS-Connect registry even though it is translated into Spanish? It has been challenging to get families to be part of that resource. Out of 5,400 participating families, less than 50 are Latino families. I would like to learn more about the barriers that you discovered as part of your community focus group. Dr. Ramirez: The emphasis on education is important. Often our communities feel that in clinical trials or participating in any kind of a study, they are being used as guinea pigs. In fact, the term *clinical trial* includes the word “trial,” which in English is the same word used for going to court. We try to use *clinical studies* and stress the need for bidirectional communication. Dr. Thrower mentioned the need to summarize research findings. As much as we ask our community for input, we need to share back what we have learned in a simplistic way. The need for bidirectional communications is important to build trust. If participants feel comfortable, they share with others and the learning community begins to grow. We are now working with our researchers to allow them to incorporate community feedback into their research design. We are just beginning to explore that in the Latino community. Dr. Bardhan: INCLUDE also has a community-based participatory research initiative on the road.

Dr. Parisi pointed out that the INCLUDE Project has now been in existence for five years. The next award cycle will fund a large cohort study to follow people with DS across the lifespan longitudinally to learn more about what it is like to live with DS. Diverse representation in this study is essential, so we hope that everyone will consider participating and being a part of this cohort project.

Dr. Bardhan thanked attendees and asked them to send in any additional questions. A recording of this webinar will be posted publicly on the INCLUDE website.

Attendance

A total of 123 people logged into the webinar.