Implementing the RAISE Action Framework
Virtual Public Meeting
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Transcript

Welcome & Opening Remarks
Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA
Christine S. Lee, PharmD, PhD, Office of Minority Health and Health Equity, FDA

Susan Winckler ([00:31](#)):

Hello everyone and welcome to our webinar today. I am Susan Winckler and I have the privilege of serving as the Chief Executive Officer of the Reagan-Udall Foundation for the FDA. The foundation is pleased to host this important discussion about our recent release of the RAISE Action Framework. If you are new to the RAISE work, RAISE stands for the Real-world Accelerator to Improve the Standard of collection and curation of race and Ethnicity data in health care. Now, before we dive in, let me give you a snapshot of the agenda.

([01:03](#)):

In just a moment, FDA's Dr. Christine Lee will provide opening remarks. Then Dr. Rodriguez-Watson will present an overview of the RAISE Action Framework, and then the bulk of our time will be invested in a panel discussion with some of our community partners. So let's just remind ourselves again why we are here today. As I mentioned, the foundation recently released the RAISE action framework, which is an innovative tool designed for leaders and providers within healthcare settings, to guide discussions about how to capture, curate, and exchange race and ethnicity data. A link to the action framework can be found in the Zoom chat now or on our website with other event materials.

([01:48](#)):

So with that, I am going to turn the program over to our first speaker, who is Dr. Christine Lee. Dr. Lee serves as the Acting Associate Commissioner for Minority Health in the Office of Minority Health and Health Equity at the US Food and Drug Administration, and she has been an extraordinary partner in this work. Dr. Lee, I'll turn it to you.

Dr. Christine Lee ([02:13](#)):

Thank you so much, Susan. I am the Acting Associate Commissioner for Minority Health and the acting director for the Office of Minority Health and Health Equity, also known as OMHHE at the FDA. At OMHHE, our mission is to promote and protect the health of diverse populations through both research and communication of science that addresses health disparities. And I'm so glad to be able to join you today and excited to welcome everyone to this webinar as part of the Real-world Accelerator to Improve the Standard of collection and curation of race and Ethnicity data in health care. We're also known, as Susan pointed out, the RAISE project. And I am especially pleased to have joined the Reagan-Udall Foundation at this stage of the RAISE project as we come together today to outline the result of your hard work. It began about a year and a half ago in January of 2023 with your first 11 webinars.

(03:11):

It was through those 11 webinars that you were able to convene leaders across the healthcare sectors to develop this framework for improving the collection, curation and exchange of race and ethnicity data. And as you might expect, my office cannot achieve our mission without continuing efforts to improve our reporting, collection, curation and integration of race and ethnicity data. To address health disparities, data has to represent the diverse communities, therefore consistent collection and reporting of data about the populations we serve, including race and ethnicity data. It's part of the foundation of advancing health equity. The work that you have put in with the workshops and the development of the framework that we'll hear more about today are an important part of helping OMHHE and FDA in addressing the incomplete and inconsistent capture of information about race and ethnicity data in real-world settings. A lack of data can limit our full understanding of the distribution, safety and effectiveness of FDA-regulated products to impact the health of the public.

(04:22):

The RAISE action framework is also a combination of the hard work of so many committed individuals and organizations who've lent their time and invaluable input to this endeavor. The hope is that people across the healthcare ecosystem, clinicians, experts in payment and reimbursement policy, federal partners, epidemiologists and those who represent patients in various communities will be able to use the lessons learned from the RAISE project to improve the collection, curation and exchange of race and ethnicity data and real-world evidence. On behalf of the Office of Minority Health and Health Equity and the FDA, I want to thank each one of you for being part of this effort. I know that your knowledge and insight has been invaluable to this project, and thank you again. I am very eager to hear the results of the action framework. And with that, I'll turn things over back to you, Carla.

Overview of Action Framework
Carla Rodriguez-Watson, PhD, MPH, Reagan-Udall Foundation for the FDA

Susan Winckler (05:22):

Christine, that was fabulous. Thank you so much for joining us and for the reminder in the grounding that we've been convening this RAISE community effort. And so it's been the work of that community that has generated the framework that Carla will be talking about. And that the reason that FDA is interested in this is because it is important to the development of medical products and for all of the work that the agency does. So thank you for your partnership on this project and we're just thrilled to work with you. So now let's learn more about the action framework that we have mentioned a few times. I am going to turn the virtual program over to the director of research here at the foundation. Dr. Carla Rodriguez-Watson serves that role so well, and she has been leading the RAISE work. So Carla, tell us about the action framework.

Dr. Carla Rodriguez-Watson (06:18):

Thank you, Susan, and good afternoon. If you've attended any of the RAISE workshops, welcome back. It's great to see you. And if you're new to this, welcome. So to refresh our memories, the reason we started RAISE was because we believe that targeted interventions can optimize value in healthcare. Health equity strategies are key to optimizing healthcare, and require community partnership, data collection and analysis to identify inequities, help set priorities and drive improvement. Key to these strategies is data. Unfortunately, many healthcare settings have incomplete capture of key data elements like race and ethnicity, which can limit opportunities to support health equity strategies. And so we launched RAISE, which Susan already spelled out, saved me some time, to facilitate opportunities

to share, learn, and build capacity to identify and prioritize solutions to improve the inclusion of race and ethnicity data throughout this healthcare data continuum that you see pictured here. So RAISE launched a series of thoroughly researched and crafted workshops to highlight opportunities along this continuum where race and ethnicity could be collected or not.

(07:44):

And starting in February of 2023, we met on the first and third Thursday of every month for five months for a total of 11 sessions. The summaries can be found on our RAISE website, which we posted in the chat, as well as our final public meeting. And we operated under the basic premise that good solutions already exist. We just needed this forum to share solutions and instigate change. And at the conclusion of that workshop series, using a robust process of polling and review, we summarized our findings into this action framework, which is also posted in the chat and available on our website. The framework includes priorities that you leaders can use to guide your efforts, specific strategies mapped to each of those priorities. And we encourage you to use this framework at your institution with the examples provided to engage your colleagues and have a larger, more in-depth dialogue on building an infrastructure for health equity.

(08:58):

So I'll orient you to the action framework. The link I said is available in the chat and on our website. Our priorities are in blue and the strategies are in purple. And we encourage partnership with community in operationalizing these priorities. And the note here highlights that there is no hierarchy to the priorities. You and your community should jump in where it best suits your needs. Because we know it's easier to conceive of doing something when you see others have done it successfully, we include examples of each of our priorities in action, and you can click on each of these links in the action framework to read more. Our first priority is outlined here, standardized data collection of race and ethnicity. And the link here points to the American Hospital Association who created a nice web-based tool that provides hospitals, healthcare systems, clinics, and health plans, information and resources for collecting and using race and ethnicity and language data from patients.

(10:09):

The next priority highlighted is training the workforce on data collection. And this really speaks to organizational reform so that staff at all levels recognize that inaccurate race and ethnicity data can contribute to health disparities. And this link points to a case study from the Icahn School of Medicine at Mount Sinai. It shows how they used a multifaceted approach for improving the capture of race and ethnicity data in an outpatient setting that culminated in a 76% improvement in the completeness of this information through its training programs. And up here on the upper right, our next priority is incentivizing data collection of race and ethnicity. And this really speaks to the need to make your leadership aware that not only is there a problem, but that there are solutions. And the link provided here is to the healthcare transformation task force, building the business case for health equity investment, strategies to secure sustainable support.

(11:17):

It offers practical examples that support a business case for healthcare organizations and professionals to pursue health equity, initiatives that benefit individuals and communities that they serve. The business imperative to address health equity gains more traction every day as the data continues to clearly show that gaps in care and outcomes based not on genetics but on demographics exist. So this report, I encourage you to go through it. It has some useful examples of how things like value-based payment models and contracting are vehicles that are supporting investment and infrastructure to improve collection of race and ethnicity data. And then our final priority here is to collect data locally

and then aggregate. And this really speaks to the need to engage with your local community to understand how they represent themselves, and then to use the many tools that are available through vendors including EHR and other platform vendors to provide response categories that reflect local preferences. And still enable roll-up to standards like those from the Office of Management and Budget value sets for race and ethnicity.

([12:35](#)):

And this link here takes you to the Center for Disease Control's ideal program, which is a community, academic and governmental collaboration to improve the collection of race and ethnicity. And then we've helpfully mapped each of these priorities to strategies to help operationalize them. This first strategy here maps to each of the priorities I just discussed, and clearly illustrates that it is a central tenant of what must happen to achieve each of the priorities, and that is to address the need for cultural humility in healthcare. We need to approach all our activities with sensitivity and humility, particularly in our trainings. We must develop and implement standardized training protocols that reflect humility in key concepts, including the purpose of collecting the data, the data's relation to health equity, who can access the data and why, and how collecting the data benefits the community. And ultimately, that should be driven by community.

([13:43](#)):

Our next strategy is to improve representativeness without overwhelming respondents and existing information architecture. So this is really about leveraging existing tools and refining them with local context in mind and doing so in partnership with community and with humility. And our next strategy here is to address distrust and misalignment between the question and the answer. This is primarily mapped to our priority for standardizing data collection because when the purpose and intended use of the data is not clear, you are not being transparent, which breeds distrust and you also get heterogeneous answers, which limits the ability for data to be made actionable. Our next strategy is to improve exchange ability of race and ethnicity information. And this is also mapped to that priority of standardized data collection because it is part of why we standardize data, so that it can be exchanged with other data sets that can provide help to build a more complete picture of a person to understand gaps in health and healthcare and drive health equity.

([14:56](#)):

This activity includes identifying technical stress points and understanding the causes, developing strategies to alleviate technical stress points and incentivizing the implementation of data standards. And on that note, our final strategy is to address resource limitations, which is really tied to incentivizing data collection of race and ethnicity. And what this will entail includes familiarizing top executives with unmet need and opportunities posed by disparities in health equity and the role of race and ethnicity to address those gaps and identify fixes. It also is about identifying and sharing funding sources, discussing opportunities and required investments and return on investments, and preparing funding proposals to meet these objectives.

Panel Discussion
Moderator: Carla Rodriguez-Watson, PhD, MPH, Reagan-Udall Foundation for the FDA
Allen Hsiao, MD, Yale School of Medicine & Yale New Haven Health System
Lenel James, MBA, FLH7, Blue Cross Blue Shield Association
Anjum Khurshid, MD, PhD, Harvard Medical School & Harvard Pilgrim Health Care Institute
Darryl Sleep, MD, Amgen

Dr. Carla Rodriguez-Watson ([15:50](#)):

And with that, I want to thank everyone who worked on and commented on RAISE. Special thanks to the office of Minority Health and Health Equity, with whom who support this would not be possible. And with that, I want to ask our panel to join me because it is discussion time. I want to introduce here Dr. Allen Hsiao. He is the Chief Health Information Officer and a pediatrician at Yale School of Medicine and the Yale New Haven Health Systems. We have also Lenel James. He's the business lead of health information exchange and innovation at Blue Cross Blue Shield of America.

([16:33](#)):

We have Dr. Anjum Khurshid, who's the associate professor at Harvard Medical School and the Harvard Pilgrim Healthcare Institute, also serves as a chief data officer at the Sentinel, FDA's Sentinel Initiative. And Dr. Alan Sleep, who's the head of global public health at Amgen. Thank you all for joining me today, joining us. And so with that, I want to target my first question to Dr. Hsiao, Allen. So Yale and you in particular have been thinking a lot about increasing diversity in clinical trials and as a means towards health equity. EQBMED is an exciting new pilot collaboration between Yale School of Medicine, Morehouse School of Medicine, Vanderbilt University Medical Center, and PhRMA, the Pharmaceutical Research and Manufacturers Association of America. So the thing that is remarkable to me about EQBMED is how thoughtful it is about really developing capacity at the community level. Can you talk a little bit about EQBMED, particularly give us some insight on how EQBMED broke through traditional constructs of clinical site recruitment and took action to foster true community partnership?

Dr. Allen Hsiao ([17:57](#)):

Sure. Thanks, Carla, and really appreciate the privilege me to join you here today on this esteemed panel. So EQMED stands for Equitable Breakthroughs in Medicine Development, and is really I think to your point, really exciting partnership that we have with our fellow academic sites like Vanderbilt and Morehouse, also Meharry and others are part of the RCMI group from Morehouse. And what I think is really key is that it also includes the community and is really a community-facing partnership where it's not pharmaceutical companies or an academic site deciding, "Oh, this is what we need and we're going to just do it," and then expecting people to flock from all over and by the way, have a nice diverse patient panel, but instead actually to really partner with the community and actually to go where the community is. So actually a large part of our work so far actually has been traveling to a bit more rural areas that are further away from the academic centers where we actually have listening sessions and meeting with community members.

([19:06](#)):

And we recognized that we just did not have enough patients who were of more marginalized minority backgrounds participating in clinical trials, which is a huge travesty because not only is it not good science, it's also I believe a health equity issue because clinical trials are such a powerful method of providing care, cutting edge care to patients that when large groups of patients for whatever reason aren't able to take advantage of them, that's a health equity issue. And certainly I think we saw that during COVID, where our minority patients were disproportionately impacted negatively by COVID. And we saw that certainly at Yale and I think nationally as well. And so I think that sort of stimulated lots of discussion, many, many thousands of conversations, I'm sure with different leaders including leaders at Yale, with PhRMA, with colleagues at Vanderbilt and at Morehouse to really hatch this program where we wanted to create this breakthrough partnership as you noted.

([20:15](#)):

And part of it is really is to focus on initially our Black, Hispanic and Latino populations that we know are traditionally underrepresented, and then to actually go out to where they are and set up clinical trial sites in the communities where typically there aren't any. But also meeting with them, understanding what their priorities are so we can bring clinical trials that are important to the community to them. And I think that's a very important distinction. It's a true partnership, not just say, "Oh, we need to do this and we'd love to have more minority patients." We actually want to understand what's important to them and be able to highlight and prioritize those kinds of opportunities. So still very much a learning program still early on, but there's so many lessons learned so far and we're just looking at ways we can break down some of these systemic barriers that our underserved patients are facing when it comes to clinical trials.

(21:13):

And also part of it is sharing best practices, lessons learned that we've had with collecting data. Lot of lessons we've learned through what RAISE and all the wonderful advice and knowledge that this group has shared with each other and certainly with us. And also pulling resources where maybe some of our community sites that don't have quite as many resources. And one of the things, Carla, you just alluded to, the importance of that and that's something we want to accomplish through EQBMED as well. So really, really interesting way where we're kind of looking at changing the whole dynamic for clinical trials and really involving the community, and we hope we have lessons learned that we can then share with other people so that this can be replicated more broadly.

Dr. Carla Rodriguez-Watson (22:01):

I love that. I love that underscoring that it's not just health equity issue, it's good science. We don't have good science if we're not including key components of our population. So in all this, Allen, what were some of the hurdles you overcame, and what do others need to do to make this partnership real?

Dr. Allen Hsiao (22:21):

So I think some of the hurdles are frankly just resources and just also people having to think outside the box or do things in a different way. Sometimes it's actually just educating the community and helping them to understand. One of the most powerful things actually is Dr. Ford, I think, from Morehouse, she was sharing how she's been one of the people meeting with folks who, some of the last survivors from sort of the Tuskegee experiments, and sharing with the community that they actually want people to participate in clinical research and not the other way around as you might think. And the reason is because they feel like that they actually sacrificed so much to further the awareness and the attention of people to change the rules. Change the laws, change the protections to protect human beings who are participating in the clinical research that to them, to your point, it'd be a complete travesty for minorities not to participate and to actually pull back. And to hear that from a committee member that they trust is so powerful.

(23:42):

So it's just so many different hurdles. It's education, it's resources, just doing things in a different way. I think also maybe even a little bit of having investigators to recognize that the input of the community is important, that it's not just what might capture their interest as an investigator, but in fact think about what's important and what are maybe opportunities where we need more attention, more research because they're very important to our more marginalized communities and is a health equity issue. So I think that whole idea of clinical research needing to focus on health equity as one of the key components, maybe a new concept for some people. So I think these are all just educational things, but

when people understand and learn more about it, I think we're not seeing the resistance there. People are very excited and very interested.

Dr. Carla Rodriguez-Watson ([24:39](#)):

Yeah, we heard that a lot in RAISE that the community themselves want to engage, but they just need to be brought in and help design, not just be the recipients of what the design is. And that story is really helpful because, as you know from being on our expert panel for RAISE, an overarching theme of the RAISE action framework was the need for community partnership and sustained infrastructure at the community level to engender trust, which is deficient. But this gives me hope that EQBMED has some tangible examples of how to make that happen. And so with that, I want to turn to Dr. Khurshid. Anjum, you've thought a lot about this as well. Can you share your experience and work with underserved communities in improving accuracy and quality of local data collection efforts?

Dr. Anjum Khurshid ([25:36](#)):

Yeah, thank you very much and thank you for the invitation and becoming part of this panel. And this is a very important topic. So I like the fact that the RAISE framework really focuses so much on the practicality and implementation of these things because we have talked about these problems for a long time. I think what we need to do is really implement solutions in our communities. And since healthcare is so driven by data and the quality of the data and the completeness of the data that we capture, whether it is for care or for research, therefore it's very important that we also develop better tools and better understanding of how we can improve this.

([26:14](#)):

It is not just the responsibility of health systems to improve the quality of the data, but it actually takes a whole community to improve that. And a few years ago, we were partnering with the Office of National Coordinator for Health IT, which is a sister agency to FDA and the HHS, to really start thinking of how could we improve the participation of underserved populations in both care and in research through improving the data collection, the quality of the data that we are collecting.

([26:42](#)):

And as you know for race and ethnicity especially, which mainly comes from self-reported data, engaging patients. Without engaging patients, you cannot really either collect or complete the data that is being provided. So we used a community engagement studio concept which reaches out to community participants but does not treat them as study participants, but actually treats them as experts who come to the researchers to inform us and educate us in terms of what is the importance of this data, what are the concerns they have, how do you build this trust? And in those conversations then, even before you design any platform for data integration or data capture, you need to understand really how the community is looking at the value of that data, especially these kinds of data that are very closely linked to identity. And it is very hard for somebody other than the person who is involved to determine what that identity is.

([27:43](#)):

And so through these community engagement studios, then we were able to engage community partners as experts in co-designing how we capture this data, what are the challenges in terms of there is mistrust not only about the data but also with institutions with the whole healthcare system in certain communities. And you have to overcome that in order to enrich the data that we can collect. And similarly, there are other technical issues as well in terms of integration of these data in terms of standards to be well-designed, especially as you think of capturing that data from outside an EHR

system, but it is still relevant to the individual that we are serving. So those were experiences that as we built these in partnership with the community, we realized that there are, even within underserved communities, there are subpopulations that have different aspects that are more important to them or which are barriers to them.

([28:37](#)):

Not everybody is homogenous even in that big category of underserved populations. So we realized that you have to really break it down to what is important for each group and be able to respond to that in order to improve the quality of the data that we are collecting. And then translate that into more standard technologies that allow for interoperability and exchange of that data seamlessly across health systems, which again is a technological problem that we have been trying to overcome. And thankfully there have been federal legislation that has facilitated both access to data by patients, but also interoperability among organizations. So I think we have to build on all these progress or advancements that have happened, but nothing will succeed unless we actively and meaningfully engage communities with respect and treat them as equals, not as just study participants or subjects that we are trying to capture data for doing our business. It's actually their business that we want to really improve.

Dr. Carla Rodriguez-Watson ([29:42](#)):

Thank you for that, Anjum. I mean, really you encapsulated it all. It's like the community, the people with whom we are trying to partner and effectively improve their care are the experts. And I love how you frame bringing them into the design, as Dr. Hsiao discussed, EQBMED's focus on. Also, thank you again for highlighting all the coordinated activity across the federal government in building tools, making incentives available to provide support for infrastructure changes to enable the collection of race and ethnicity and other data, which I know Lenel wants to jump in and talk about. But before we do that, I'm going to turn to Dr. Sleep. Darryl, you and I have talked a lot about how the lack of data to characterize the health status and utilization of treatments and care of historically underserved populations is a healthcare ecosystem problem that requires a healthcare ecosystem solution. Those are your words from bio. So what role has Amgen and life sciences in general played or can play in supporting the priorities and strategies highlighted in the RAISE action framework?

Dr. Darryl Sleep ([31:04](#)):

Yeah, thanks, Carla. So you actually took the words out of my mouth in terms of the healthcare ecosystem problem. So I think maybe one way to frame it up, I think that not only is Allen and both already said right now, critically, why is it important to generate data that is representative of all patients that are suffering with any particular illness that we're dealing with is because it's mandated and it's required by the FDA, right? We have to do this in order to get our drugs approved, but that's fundamentally the sort of carrot, if you will. The real issue is highlighted by Allen, and I'm sure that Lenel is going to talk to this, is that if we don't do this, if we don't improve and achieve full representation and generate the data and include underrepresented populations and underserved communities in these clinical trials, not only are we not improving or readdressing health inequity that exists or the inequity that exists in healthcare, but we're actively perpetuating and exacerbating it.

([32:17](#)):

So for me, this is a moment in time and I think we learned this through COVID, where we all need to join arms. We all have a shared common purpose, a shared common objective here. And this is time for action. Anjum said that we've been talking about this for a long time and I completely agree with that. So I think some of the things that we can do, and I think that the key area here is that not only is clinical trial participation important to generate the data that is going to inform the appropriate use of

medicines and improve the treatment of underrepresented communities, but participant in clinical trials is actually part of the disease care continuum for many of these underrepresented populations.

([33:11](#)):

If you have an illness, then you're at the end of the tether. Clinical trials become part of the disease treatment continuum. So it's critically important that we actually bring the clinical trials to the patients where they're being treated rather than taking the patients out of their clinical medical community or where they're receiving their healthcare and taking them to the clinical trials. So a couple of elements there, number one is bringing the study to the patient in the community. And we've already heard that requires community enhancement, building up the community, community engagement, and ensuring that the community's voice is brought into that to redress the mistrust. But critically important related to that is that the investigators need to be trained. And so a couple of programs that I think we should highlight here and that we should really continue to encourage besides what Yale is doing as part of EQBMED, which is there's an element of training the investigator there.

([34:22](#)):

There are a couple of critically important partnerships and collaborations that are occurring within the healthcare ecosystem. The first perhaps is a group called Beacon of Hope. This is led by the Novartis US Foundation that is partnering with the historically Black and Brown communities and universities along with industry to train the future principal investigators and investigators to serve in the communities and bring the clinical trial to the community. The second one I'd like to highlight is the Winn Awards, Clinical Investigation Awards, which is another partnership. And the BMS Foundation in partnership with a number of other life sciences and life sciences communities seeking to really improve and bring the training for clinical trial and expertise in clinical trials to the investigators that will ultimately be representative of the communities and the patients in which that they're treating and representing. So it's critically important that as life sciences, and we have the opportunity here as life sciences has been a critically important part of the clinical trial infrastructure, and therefore a critically important part of a potential solution for redressing health inequity and inequity in healthcare system and how healthcare is delivered to really join forces.

([36:16](#)):

We can't do it alone. No institution can do it alone, and the community certainly can't do it alone. This is a time to bring everyone, the entire healthcare ecosystem together, together to find a solution not only in the short term where we can actually potentially do this for a particular study in a particular disease area, and then once that study is done, the infrastructure disappears. But to build sustainable infrastructure within communities, built with the community, with trusted leaders within the community, with investigators that are from the community that are highly trained, with the infrastructure and the resource support wraparound that can provide sustainable clinical trial sites in communities that are underrepresented across the country.

([37:14](#)):

We're working with a couple of communities certainly in the LA area and other parts, but it would be great ultimately the work that we're doing at EQBMED, the work that Amgen is doing and the work that other life sciences companies are doing, that we can pull these resources and expand it. Scale these solutions to upon hundreds of communities across the nation, such that underrepresented communities, patients who really need these treatments can actively participate in clinical trials. And that'll go a long way to dressing the inequity in healthcare that exists across the country.

Dr. Carla Rodriguez-Watson ([37:59](#)):

Thank you for sharing that, Darryl, particularly the information about what you're doing, how Amgen and you are involved with EQBMED as well as with Beacon of Hope and the Winn Awards. We put those links in the chat. And wanted to, I think some of what we also talked about a lot I'd like to hear your thoughts is how do you take this work that we're doing within the US, and how does a life sciences company like Amgen, because you don't make just products for us, think about expanding this work globally and how do we improve access to care globally? I mean, access to meds and clinical trials globally?

Dr. Darryl Sleep ([38:44](#)):

Yeah, no, that's a great point and it's something that we are working actively on along with other companies. But I think one of the critical issues in the US right now is clearly on race and ethnicity lines, but that's not the only underrepresented groups within clinical trials and not only where the inequity and the disparities exist. And certainly there are disparities that exist along gender lines and conducting clinical trials in parts of the world where traditionally we don't go because the infrastructure doesn't exist.

([39:29](#)):

Now, one of the critical important elements there is of course, and it's the same thing for our communities in the US, is it's unethical and inappropriate to conduct clinical trials on and in patients where there's no intention of ever making the drug available. So it's critically important that we find solutions for sustainable access to the medicines that go beyond perhaps any of our individual companies commercial interests. And so we're working very closely with groups, NGOs and other organizations, particularly in non-communicable diseases right now where I think in the communicable diseases with HIV, malaria, tuberculosis, there are solutions that are in place with vaccines and redressing the inequity and in treating and preventing communicable diseases.

([40:28](#)):

The opportunity exists really to really expand that and find those partnerships for non-communicable diseases and thinking really across the board in India, in Africa, in parts of Latin America, Asia, where traditional access to clinical trials, traditional access to medicines is substandard. Low and middle income countries, particularly the very low income countries, there are a lot of opportunities to find solutions and learn from solutions that were brought to bear in the communicable diseases spaces. So we partner with several NGOs in a traditional philanthropic approach, but philanthropy will only get us so far and we need to really work on finding sustainable solutions and sustainable distribution networks for our medicines that are able to redress those inequities and the disparities that exist elsewhere. So a lot of work to be done there, but the good news is there are a lot of companies like ours including BMS, Novartis, Merck, AZ, and others that are really actively engaging in this space with partners across the world.

Dr. Carla Rodriguez-Watson ([41:51](#)):

That's so exciting to hear, and I think what I heard you say is in the sustainability, not just of the sustainability of the trials infrastructure. As you said, participating in clinical trials is really becoming an extension of care for some of these communities. And therefore, providing the infrastructure in the trialists and the providers as well as the data infrastructure to support collecting information and being able to provide that for the community and for the clinical care ongoing beyond that of the trial. Super important, and also want to thank you for sharing that. And what I'm hearing in the translation to globally is the same kind of strategies and priorities that are outlined in the RAISE action framework to really work with the local community, regardless if they're, I know outside the US they don't have

concepts of race. But the tenant is the same, that you need to engage with that community, understand those different groups and what are their priorities and how do they see health equity, and build and design and include them in these trials going forward.

([43:11](#)):

So thank you for that. And now I want to turn to Doc Mr. Lenel James. Lenel, Blue Cross Blue Shield of America has been really one of the industry leaders in incentivizing the collection of not just race and ethnicity but social determinants of health data in a standardized and interoperable way. And not just among your members, but across Blue Cross Blue Shield's provider networks. Can you speak to some of the challenges your partner organizations identified and eventually overcame to develop and implement infrastructure to support standardized data collection and exchange ability? Who do you need to get on board and how did you do it?

Lenel James ([44:00](#)):

That's a great question, Carla. Thanks for the invitation and thanks for the opportunity to work with this crew. And hopefully we'll stay in touch because there's a lot of things I'm involved in and we probably should all be talking. In addition to working at Blue Cross Blue Shield Association for the last 20 years on their data strategy and interoperability team, I'm on the board of directors of HL7. And actively involved in the standards initiatives for the industry as part of my work with the National Committee for Health and Vital Statistics where I'm one of the newest members and I'm on my second year and we've been looking at the SDOH as part of that. So I've been seeing it from the payer concern, from the industry standards concern, and then the implementation with all the stakeholders that payers work with that, again, I just got back from the US Aging's 49th annual conference, and it was all about health equity and how to reach the community, which they do in their AAA capacity, they outreach.

([44:59](#)):

So your question is really on target. In terms of the how, at the association, many of you may know we have 33 Blue Cross Blue Shield plans across the country covering, actually we have a person in every zip code in the United States has got coverage through Blue Cross or the federal employee program where we've got 60% of the employee programs. I mentioned all that just to say this is a challenge we're very sensitive to because our board of directors, who is the CEO of each of the 33 plans, three years ago, voted that we were all in on health equity. And as part of that, I was assigned to be part of the data strategy team. So one of the things we did first was to get several million records from our plans and we researched what was in them to find out what percentage had race and ethnicity data, what percentage had language, what percentage had SOGI data.

([45:56](#)):

I can't go into the details of it because I don't have all that in my head, but I can assure you the statistics we got were not impressive and were of a concern. So we've been based on that data, we initiated a project to actually build a specification so that we could exchange the data following the standards of CDC REC, the CDC Race and Ethnicity Code Set, which is also at the NLM National Library of Medicine at the Value Set Authority Center. So it's the place where standards live, and those standards have been actually been worked on by HL7, updated by the office of the national coordinator.

([46:36](#)):

As some of you know, the US coordinator for interoperability is currently on round three that's actually out for EMR vendors to certify that they can capture and exchange those fields. We built at the association our own copy of that spec to make sure we were having our plans collect and outreach to

that data using the standard that's been recognized by CDC Race and Ethnicity Code Set, and also the language code set that comes from ISO, International Standards Organization, has a US version that's in.

([47:15](#)):

So one of the things we found is this is a lot harder than it looks. So we're on year three of that effort. Seeing the percentages, working with the plans to determine other ways to incent people to exchange the data. And as many of you said, people want to share the data, but we surveyed and talked to 90 people, not all of them with Blue Cross Insurance. And it turns out people will share that data, but the key thing is you have to explain why you're asking. And one of the examples they used was the Evanston Library in Chicago did a survey of their members, and when they asked them and explained this was for research to make sure they could have the appropriate diverse reading material, people were willing to exchange the data. So it is very important to not only ask for it, but ask for it the right way.

([48:09](#)):

The other thing I'll wrap up in terms of as we did the technology, to my surprise, there are a lot of entities and organizations that don't realize these standards that are interoperable and can work in X12 for claims, can work in CDA for clinical data exchange, and can work for FHIR, Fast Healthcare Interoperable Resources, which is an API. The thing you use for Amazon, there's a healthcare version of that. All three of those can point to the right code sets for collecting that data. The challenge is many, not the whole industry is aware that those codes have been used at the HL7 terminology group to make sure they're updated, accurate. And one last statement, Carla. I've traveled to Germany and Australia, and guess what? Racism's everywhere. It's just different. In Australia, its Aborigines don't get treated like everybody else. In Europe, it's gypsies don't get treated like everybody else.

([49:14](#)):

So when I talk to my peers, this health equity is everywhere as a challenge to not only the United States but the world actually. And we're happy to say we're working on those standards interoperably and internationally at HL7. So hopefully that helps you have a piece of how big this problem is and the fact that there actually is some very impressive work going on at the [inaudible 00:49:44], CMS, and the payers and providers are actually working on this heavy duty. And it's a big lift, but the reward will be better data to verify which efforts will really work.

Dr. Carla Rodriguez-Watson ([49:57](#)):

Awesome. Lenel, thank you so much for that. And I think there wasn't a RAISE priority or a strategy that you didn't hit, and that's probably because of your engagement on RAISE, as well as some of your colleagues from some of your plans. I just want to underscore what you said again, basically that your leadership elevated health equity on that pedestal and made it one of your core foundations that really drove, that's helping to drive all this engagement that you and your organization have put towards addressing these problems. And also, again, highlighting there are tools out there, folks, we could use them. And with that, I want to turn now to Anjum. Dr. Khurshid, as the chief data scientist for Sentinel Operations Center, what do you see are ways to improve the inclusion of race and ethnicity in surveillance systems like the Sentinel Program, which by the way are leveraging data from payers like Blue Cross Blue Shield ultimately, and health systems like that of Yale New Haven Health System and others. So Dr. Khurshid, your thoughts please.

Dr. Anjum Khurshid ([51:10](#)):

Yes, thank you so much [inaudible 00:51:11]. And this is a wonderful discussion, and then I'll thank you for also getting into the details of what it takes to really make this data available in a systematic fashion

across the health system, which otherwise seems very fragmented, but I think there's, as we had discussed, there are tools and there are rules that are trying to overcome those challenges. And so Sentinel is a good example of a national surveillance system, which again, I think is a great resource and asset nationally because it is one of the largest public health data access programs that allows us to be able to systematically look at evidence from a scientific perspective at a population level. And it has more than 120 million patients accruing data every year into that system.

([51:58](#)):

Although for those who may not know, Sentinel is a distributed data system. So really we work with partners who collect data and then we query that data, but in order to ensure that the data is of good quality and it is stable across years because it's longitudinal studies that usually have to be done in order to understand drug effectiveness and drug safety that we use a Sentinel common data model that was developed over the last 10, 15 years. Has been also, I think used nationally, internationally as well as an example of how you can systematically do pharmacovigilance using data that has been well-defined. And so the Sentinel common data model also has, it has many tables, but one of the tables is specifically on demographics that tries to capture race ethnicity.

([52:47](#)):

But again, I think it emphasizes the point that this is not a top-down approach. We can't just mandate that everybody should just collect race, ethnicity data and it'll be just, every data set will have that information. It has to come from the bottom up in terms of working really at the granular level that other panelists have described. How do you improve that data? And then Sentinel traditionally, and many of the surveillance systems have relied on claims, which is where health insurance companies, because they have been paying for these services over a period of time and those data are much more standardized and complete in terms of encounters. And yet I think we are also finding that race ethnicity data may not be as complete in a lot of the claims data as well.

([53:31](#)):

And so there are efforts by insurance companies also to improve it. But the other source of data where we can capture a lot of this race ethnicity is the EHR data where clinical encounters take place. So the Sentinel system has also been very actively pursuing the ability to be able to capture information from EHRs and connect it to the claims data so we can have a much more enriched dataset to be able to understand how some of these race ethnicity variables affect us. So currently that common data model, we are in version 8.1, 8.2 right now in the common data model, but it actually captures the disaggregated race and ethnicity according to whatever was the last standing OMD directions.

([54:15](#)):

And we will be updating that as these new directions come in, but a lot of it also relies on our partners being able to capture that data from either claims or EHRs effectively. But the size of surveillance systems also allows us to understand some of these dynamics and how they affect outcomes. And one example would be during COVID, where we did a study using the distributed sentinel system to look at COVID outcomes by race ethnicity. And despite the fact that, again, as I mentioned, that those elements are not necessarily captured in every encounter. But we were still able to see some of the disparities that happen across these race ethnicities, especially Native Americans compared to other groups. So I think there's an opportunity to really build this national resource and keep on increasing its effectiveness in terms of helping us do these national level and regulatory scientific studies to understand the dynamics of how some of these things affect it. But again, going back to the original RAISE framework, that that cannot happen without an active engagement of patients and communities.

Dr. Carla Rodriguez-Watson ([55:30](#)):

Thank you so much, Anjum. Again, emphasizing the need, especially in the distributed framework, that we need to act locally, each of these partner organizations. I want to thank you all for engaging in this discussion, and now hand it over to our chief executive officer, Susan Winckler.

Closing Remarks & Adjourn
Susan C. Winckler, RPh, Esq., Reagan-Udall Foundation for the FDA

Susan Winckler ([55:48](#)):

So let me just echo Carla's thanks. It was so refreshing to hear that there are challenges and solutions emerging from so many parts of the healthcare ecosystem. From healthcare providers, from payers, from researchers, from the biopharmaceutical industry, and that this is important and hard work to do. We want to improve equity and access to healthcare delivery and to research. And to assure that the medical products that are developed, that new medicines are tested in people who look like and live like our population. So I have to thank these healthcare communities so generously shared their experiences and expertise as we were going through the RAISE process. And I'll just underscore as we close out that the time to act is now. There is a lot that's happening to support data for health equity. The call to minimize the space between clinical care and clinical research, that data standardization and exchange ability is critical to that.

([56:54](#)):

There are exciting incentives in alternative payment models and there is technology emerging to support these efforts from the office of the National Coordinator, as Lenel mentioned, to many other components to help us with a standardized and an interoperable means of collecting and exchanging this data. The programs like EQBMED and Beacon of Hope are other multi-stakeholder components that are helpful. So I would just say from the foundation's perspective, and with our thanks to FDA and to the entire community for partnering on this, we encourage you to use the action framework and then share your experiences with the action framework. You can share those with us by contacting RAISE@reaganudall.org, and we'll add them to our research page. So with that, thank you so much for joining us. Share your experiences, share your solutions, and the foundation is here to help. Take care.