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ADMINISTRATION

U.S. Food and Drug Administration

REACH Roundtable: FDA & Rural Communities

THURSDAY, APRIL 18, 2024
11:14 A.M. TO 1:09 P.M.

LIST OF PARTICIPANTS

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- **Casey D. Xavier Hall, M.P.H., Ph.D.**
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- **Becca Hayes, M.D., M.E.H.P.**
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- **Kathleen Kennedy, Pharm.D.**
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- **Billie Jo Kipp, Ph.D.**
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- **Bon Ku, M.D., M.P.P.**
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- **Christine Lee, Pharm.D., Ph.D.**
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- **Hilary Marston, M.D., M.P.H.**
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- **Perla Nunes**
  REACH- FQHCs
- **Stephine Poston, M.A.**
  REACH - Tribal
- **Jason Roos, Ph.D.**
  Mission Office Director
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- **Darlene I. Santiago Quiñones, Ph.D., MSc**
  REACH – Puerto Rico
- **Todd Seto, M.D., M.P.H.**
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- **Haider J. Warraich, M.D.**
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- **Tony Welch, B.A.**
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- **Frank ("Frankie") Y. Wong, Ph.D.**
  REACH – Community Centers

PROCEEDINGS

(11:14 a.m.)

DR. LEE: Thank you so much.

Tony just mentioned to me, we do have a transcriptionist here today, so we do have a reminder for everyone to please use their mics when talking, and please state your name. We have a little sticker at the bottom of it for the transcriptionist to know who is talking. For example, I will say "Christine Lee," and then go into my conversation.

Before we move forward, I did want to take a few minutes to turn it over to Ms. Perla Nunes to go over a quick recap of what happened yesterday at the panel. Now, the interesting thing about the panel yesterday was the clarity of the key messages that came out. It was so clear that LinkedIn was able to succinctly point out what were the 3 to 5 clear messages throughout different people listening in, so I thought that was quite good.

Ms. Perla Nunes, can you go ahead, and then we'll turn it over to Soad.

MS. NUNES: Good morning, everyone. Buenos dias. Perla Nunes. The discussion not only shed light on the challenges and barriers amongst various communities, but the panelists also proposed solutions for enhancing community participation and research.

Sharing some of the key points, we need to bring clinical trials to the community and establish local sites that are convenient and staffed by individuals who culturally and linguistically align with the community. Panelists stated that many of their patients and community members said that they would, a hundred percent, participate; however, they are not being asked. We need to reach out more proactively and make sure everyone knows they're invited to join.

We need to improve our communication by stripping away the intimidating jargon that often alienates rather than informs. It's important to make communication heartfelt and comprehensive, while also training our research staff and investigators to do the same. The panelists represented many different cultures and races; however, the most common theme amongst all the cultures was trust. We talked about the importance of being open about how participants' data is used and ensuring they remain informed long after the trials conclude.

Lastly, our focus should also be on cultivating lasting relationships. The power of building genuine, bidirectional relationships with communities was emphasized as essential for meaningful and sustained engagement, and it finishes like this. "Today's panel reinforced that true commitment to making clinical trials more accessible, ethical, and effective involves more than just temporary initiatives and requires a persistent collaborative effort."

DR. LEE: Thank you so much.

Soad?

MS. ABBADI: Hello. Good morning, everyone. I would like for us to do introductions and an icebreaker because there are a lot of people, and names, and titles, and REACH affiliations in the room. But before we dive into introductions, I did just want to quickly provide some context on how we got here today.

On January 11th of 2024, just this year, we had the first roundtable, and it was the first time our REACH Consortium got together to introduce themselves to each other. We were kind of operating in these virtual silos, and what we were finding is there were a lot of overlapping initiatives and projects amongst the REACH Consortium.

Like Dr. Marston mentioned Puerto Rico, Hawaii, faith-based and HBCUs, tribal nations, federally qualified healthcare centers there are a lot of overlapping initiatives. And what we found from the first REACH roundtable, just a few months ago, in January, was these overlapping similarities, but also some stark differences in nuances, which I think we're going to talk about a little bit today.

But really, the three key takeaways from the conversation, the first roundtable, was to have a sustainable model of trust. And we're going to talk a little bit about what trust means because I think trust means something different for everyone, and I think there are trusted members of the community, but that term is so ambiguous. Who are those trusted messengers? Who are those community champions?

Then also, an ask of REACH was to be able to cultivate a learning environment, to be able to share study instruments, focus group questions, scripts, town hall questions, and moderator guides.

So how do we, instead of not having those opportunities for collaboration, really collaborate with each other?

We'll talk a little bit about how we've talked about study instrument sharing as well, and then to develop a talent pipeline by building the next generation of clinical trial investigators, specifically trusted members in their communities, but also providing professionals and paraprofessionals in those communities with opportunity to develop the talent pipeline.

So what has been done since just January of 2024 and I just want to remind everyone that REACH stands for Racial and Ethnic Minority Acceleration Consortium for Health Equity. I know we have a lot of acronyms in government, and I'm going to try my best not to use too many acronyms. It just started in June of 2023, so it hasn't even been a year yet that REACH has launched, and folks are in the midst of working on various projects throughout the center.

So for trust, what does that look like, building trust? The answer was, cultivating and building a sustainable model of trust, it doesn't just stop. It is ongoing. It's an ongoing model. We have monthly checkins with each REACH member, and I don't think they're monthly. I think they're actually weekly.

All of our team with the Office of Minority Health and Health Equity meet with our REACH Consortium and members at least monthly, maybe even weekly. We have each other's phone numbers. That's really how we cultivate that genuine relationship with our REACH Consortium and how they also build those genuine relationships within their communities. They're actively present within their communities; then always asking for permission to share their findings.

I think that's really important because as they're conducting town halls and focus groups, we want to be able to report back, and we want to make sure that we are relaying the message in a way that is appropriate, but also asking for permission amongst our REACH members and saying is it ok to share this information with the centers and with some of the individuals here.

And lastly, really aligning the work that they're doing, whether it's opiates, or food allergy disparities, or biologics, or diabetes, or homeuse medical devices, how are we aligning their work with subject matter expertise at the FDA level, so really identifying who those trusted champions are at FDA, as well. Then we did have an opportunity for them to network and engage in person yesterday with the centers at FDA because, again, CFSAN, CBER, CDRH, all of that is just acronyms, so really explaining what the centers are doing and how there can be alignment within the REACH Consortium and their communities, but also with the FDA centers.

Then for the study instrument sharing session, I know Yvonne and Julie facilitated a great study instrument sharing session to be able to share and cultivate that learning environment amongst our REACH Consortium and partners to be able to share those study instruments. You're not alone. You don't have to reinvent the wheel. There are already study instruments that have been created as prototypes, and how do we cultivate that learning environment?

Then lastly, to develop a talent pipeline, really building that next generation of clinical trial investigators and empowering folks within your own communities, rural communities, pharmacists that are already in your communities, HBCU students, students that are in the process of being trained up. So how do we train up the next generation of clinical trial investigators, but also providing fellowship opportunities as well? And we did launch the fellowship in Genomic Science and Health Equity. We received a number of applications, a couple of candidates from Hawaii as well, so I'll thank Deb and Todd for that.

So in closing, there's still a lot of work that has to be done, but more importantly, how do we deliver on our promises? I think we don't say we're going to do something without really doing it in a timely and efficient manner. And the same way that REACH builds trust within their communities and you>ll hear about that a little today I think that's a model for how FDA can build trust with REACH, and how HHS can potentially build trust with REACH as well, so thank you for that.

I am going to ask everyone to go around. I don't think we have much time for introductions, but just in 30 seconds, your name, your REACH affiliation, and what you're hoping to get out of this conversation. I'm just going to go clockwise, and if you can speak into the mic; just press the button. There is a transcriber, a captioner, that is looking up on that camera. It will not be broadcasted. I do want to share and preface that. This is strictly for notetaking purposes, and anything that will be shared, we'll be asking everyone's permission prior, so thank you.

MS. NUNES: Perla Nunes. I represent REACH FQHCs, federally qualified healthcare centers. What I hope to be able to get out of the REACH program is that our communities are asked to participate. We listen to their feedback, and we repeat it as many times as we need to in order for them to make their decision whether they want to participate or not.

DR. ROOS: Thank you.

Jason Roos. I'm with the Department of Health and Human Services, Advanced Research Projects Agency for Health, also known as ARPAH. As a research funding agency that is invested in highimpact research, one of the things I'm interested in very much today is, first of all, just listening and hearing from all of you as to where we think about our investments for the future, how can we really make sure that our investments are focused on rural health, and how can we do a better job of extending the reach of medical innovation into that space.

DR. TAIRA: I'm Deborah Taira. I'm from Hawaii, and I'm hoping to share with you some of the stories or paint a picture of rural health in Hawaii. But also, I'm a health economist, so I want to show you how there's value in investing in rural health.

DR. HAYES: I'm Becca Hayes. I work with Perla. I'm representing FQHCs REACH in North Carolina. My whole career has been in FQs, and I think my main goal here is to figure out how I can bridge that gap between the incredible network that is federally qualified health centers across the country and clinical research because they are ready, they're excited, and we just need to figure out how to bring those two things together.

DR. DILLON: Hi. I'm Kristen Dillon. I'm the Chief Medical Officer for the Federal Office of Rural Health Policy. I'm a rural family physician, and I am here partly to listen and learn. One of our roles as the federal office is to work across Health and Human Services to bring the voice and the context of rural health to everything else that our government tries to do.

I really appreciate so many of the folks in the room for being proactive in your outreach to us so that we can help you engage with rural communities across the country. So there's the learning, listening part, and then I'm also just here for marketing because we are here as a resource. We fund the state offices of rural health. We have connections with critical access. One of our big things is just to be a giant, I don't know, octopus, reaching out into America's rural communities to help them come connect with you all, and vice versa, to improve health for rural Americans, so thanks for having us here.

MS. POSTON: Good morning. I'm Steph Poston. I'm from the Pueblo of Sandia, and I represent the Tribal Reach Initiative, and I'm hoping to get out that our tribal people have the right to improve healthcare and to utilize the network and REACH opportunity to make those improvements, especially in our rural tribal areas.

DR. SETO: Aloha. I'm Todd Seto. I'm a cardiologist from Hawaii. I work at the Queen's Health System, which is a large health system that spans across the whole state, the six islands. We have a very good, distributed network of primary care providers. We do have decentralized clinical trials, thinking about it. We've done clinical trials in the community, hula halaus in the community, looking at diet.

The goal for me is to understand how we can use our network that exists that we've been using for more behavioral or dietary clinical trials, two or three that were NIH funded, and how we can use that network and develop something that's more tailored for energysponsored trials, in particular, which is a different kind of study, different kind of needs, and learn what we need to do to build that.

MR. WELCH: Good morning. I'm Tony Welch. I'm the Associate Director for Outreach and Communications for the FDA Office of Minority Health and Health Equity. I've already learned so much from the REACH members about their work in communicating with and reaching out to the communities we serve, and I want to continue doing that. Thank you.

DR. COOPER-WILLIAMS: Good morning, everyone. I am Jasmine Cooper, Director of Qualitative Research with the PATIENTS Program, and I'm a part of the REACH faith-based and HBCUs project. I think one of the things that I am most interested in doing during this time is helping to elevate patient voices from rural Southern Maryland to seat to the table such as this. They can't be here, but I can, and I can convey the messages about their needs that they deliver to me, so elevating patient voices in spaces of powerful people who can make moves towards health equity a bit further can do.

I think the other thing that I want to get out of this experience, that we've already been getting, is the collaboration, and seeing some of the parallels with projects that are in Hawaii, and projects that are with the tribal communities, and seeing similarities with what the needs are, but also the distinct ways that each of these communities have specific health equity desires and specific health equity means that we need to tailor our approaches to be able to meet a little further.

DR. KU: Hi. I'm Bon Ku. I'm a program manager at ARPAH, working with Jason. I'm also an emergency room doctor. I believe in these opening remarks, that technology is an enabler. I just started a program called PARADIGM, which is around delivering advanced hospitallevel care outside of the walls of the hospital. I really believe that 80 percent of what we do in the hospital can be delivered outside of those walls. There are advanced mobile health unit vehicles. And I'm here to listen. I'm here to see how technology can enable you who are on the ground, and to shape what the program PARADIGM might look like, so thank you, everyone.

DR. MILLENDER: Hello. My name is Eugenia Millender from Florida State University, and I am here with two of my colleagues and two of my community partners. Specifically, I am interested in how to understand a little bit about different organizations, but we are here with migrants and immigrant populations that typically are the ones who are cultivating the agricultural situations in South Florida. Those are the ones who are mostly the individuals who are indigenous from Central America and Latin countries.

It will be nice to know how can we provide more resources, such as clinical trials that will impact them directly as individuals who cultivate the land and who also see it more as a cultural, respectful way of doing and providing for individuals, so happy to hear more and happy to see what's going on in the future.

DR. HALL: Hi, everyone. I'm Casey Xavier Hall. I'm part of the same Florida State team. I am excited to talk a little bit more about technology and how to leverage technologies in a smart way. Our project with REACH is focused on decentralized trials and how to best leverage technologies with minority populations. Another unique aspect of our project is we also focus on LGBT populations and a variety of racial backgrounds as well, so our team has different population expertise represented.

DR. HSIEH: Good morning, everyone. My name is Julie Hsieh. I am an epidemiologist by training, and I work with the Office of Minority Health and Health Equity. I work really closely together with our six REACH partners, and thank you for coming today.

DR. SANTIAGO: Thank you. Good morning. My name is Darlene Santiago. I'm from University of Puerto Rico. I'm in the Puerto Rico REACH Consortium. I'm excited to be here. I have two main goals for this morning. The first one is I hope I will be proactive and successful at painting a picture of Puerto Rico and the necessities that we have, specifically in the rural areas, but also get you all so motivated that you want to come to Puerto Rico and visit us.

(Laughter.)

DR. SANTIAGO: So those are my main goals for today.

DR. ITURRIAGA: Hi. Erin Iturriaga. I am a new branch chief at NIGMS, National Institute on General Medical Sciences, and my branch oversees the CTRs, the clinical translational research networks, as well as the NARCH programs, the Native American Research Centers for Health. My goals today, really, are to meet some of the people who I'll be working with as a new branch chief, as well as learn from everyone, and also take it back to my institute so that we can learn, and learn how to do things better, and I'm taking lots of notes.

DR. WONG: Hi. I'm Frankie Wong. I'm from Florida State, too, and I'm here to obviously listen and learn because this is my first exposure to FDA. So it's a whole different ball game for me because my background involves NIH related work, so it's a very different thing. In some way, it kind of brings me full circle because before I came back to academia full time, I used to deliver services in the community, like immigrant refugees, exoffenders, and people living with HIV. I used to work in the Bronx. So this is really enriching, to be able to share and then to reconnect with old colleagues from Hawaii.

DR. WARRAICH: Hi, everyone. Thank you for being here. My name is Haider Warraich. I'm a cardiologist, and I work at FDA as a senior advisor for chronic disease. I just want to take this time to really thank all of the REACH members for traveling from all over the country to come and join us and be here. I think this is a truly enriching experience for us to hear from your voices directly in person.

I'm also super grateful for all the external folks from the government who joined us, starting with Dr. Clancy. We have Kristen Dillon who's flown from Oregon, and then we have Jason Roos and Bon Ku from ARPAH, and then from NIH, we have Erin and Dawn Morales. So thank you all for coming here. I'm just very excited to listen and learn, and hopefully turn that into action.

MR. GONCALVES: Good morning, everybody. My name is Joao Victor Santos Goncalves. I am with the FSU consortium representing the GuatemalanMaya Center in Lake Worth, Florida. We serve farmworker communities largely comprised of indigenous Guatemalan Mayan migrants that fled the Guatemalan genocide in the 1980s.

To underscore much of what Eugenia was saying, many of our communities are farm workers. They are agrarians, they are day laborers, they are the people that take our food. So I'm hoping to bring back today this whole activity to them. You'll see my notepad full of stuff. It's like, "Alright, guys. Here is what we are going to do." I want to bring actionable strategies to them to excite them, so that we can improve their health outcomes.

DR. MORALES: Hello, everyone. I'm Dawn Morales from the National Institutes of Health. I'm the Director for Rural Mental Health Research and American Indian and Alaska Native Mental Health Research at NIMH, National Institute of Mental Health, and I am embedded as a project scientist on three large health disparity clinical trials because I'm a statistician and methodologist.

I'm also an active part of the ISPCTN, IDeA States Pediatric Clinical Trial Network, which is an NIH clinical trial network situated in rural, remote, and tribal settings, where we run clinical trials through those sites, and I am here to listen and learn.

MR. APARICIO: Good morning, everyone. My name is Boris Aparicio. I am with the REACH Community Center, specifically Compass LGBT Community Center in Lake Worth Beach, Florida. And while I'm also here to continue my center's goals of advancing the lives of LGBT individuals and those affected by HIV and AIDS, I'm also here to identify other agencies and strategies, helping our local rural communities that span not only Palm Beach County, but South Florida, in general. Thank you.

DR. KENNEDY: Good morning, everyone. My name is Kathleen Kennedy. I'm the Dean of the College of Pharmacy at Xavier University of Louisiana in New Orleans, so I'm a member of the faith-based and HBCU consortium, REACH Consortium. Prior to being dean, actually I led the community engagement outreach core for our CTR, which you just recently heard about. So I'm excited about the opportunity to continue that work and to elevate the voices of our community, in particular the African American community in New Orleans and throughout the state of Louisiana.

DR. LEE: Good morning, everyone. I'm Christine Lee. I'm currently the Acting Director in the Office of Minority Health and Health Equity. Thank you for being here. We're so appreciative to listen and learn. I guess one point that I hope comes out of this meeting is that the "A" in REACH really happens, which is the acceleration piece. I think that you might have all heard that REACH was created 10 months ago, and already in the last 10 months, I think we have been moving at an accelerated pace to really advance health equity, make those connections needed to be made, build those relationships, and extend our network.

I do want to say one more thing. Dr. Clancy, when I started in the government 12 years ago, you were the first name I heard, so it's so great to be able to sit next to you today.

DR. CLANCY: Well, thank you, Christine. Carolyn Clancy. I'm not sure if I want to know how it was that mine was the first name you heard

(Laughter.)

DR. CLANCY: -- but I'll take it as a lovely compliment.

I work for the Veterans Health Administration now. I basically tell people I'm the dean because I've got leadership, and we created an acronym for the name of our group that is DEAN. I basically have all of the academic affiliations, so you may not know that we support the training of a third of the U.S. medical residents, and that's only the beginning, and about 60 other disciplines as well.

We also have a research program, which is pretty impressive and amazing, depending on what day you're asking me about it, but it's intramural, so the notion of collaborations in this area would be very helpful, and a group focused on healthcare innovations and, like I think everyone who's awake and breathing, focused on AI as well, because we're all completely losing our minds about it.

What I find most fascinating, and very much echoing the comments of everyone who's talked about listening and learning, is that the FDA would bring its lens to this, because I think that is just a very, very powerful and important dimension to all of this. I'm also interested in figuring out how do we make it easy.

I want to say somewhere between 30 and 35 percent of the veterans we serve because we don't get to choose our markets we're serving veterans where they are, who live in rural areas. And I'm not talking in Leesburg; I mean, fairly remote areas, and we could have a longer conversation about why that is, maybe. But that means core business for us is figuring out how to reach those veterans. And I'm going to guess that many of you have veterans in some [indiscernible] profession involved in the work that you're doing.

And I'll just close by saying I'd love to come to Puerto Rico, my husband and I go to Hawaii about every year, and New Orleans is always on my list.

DR. BAQUET: Hello. I'm Claudia Baquet, and I lead the University of Maryland REACH program, which is a partnership with Xavier University of Louisiana College of Pharmacy and Coppin State University School of Nursing in Baltimore. I am a former fed. I knew Carolyn for part of my NIH career, we overlapped a little bit. I worked as the Maryland AHEC director for 13 years when I was at the University of Maryland and with the Federal Office of Rural Health Policy, so I'm delighted to see all of you.

Our commitment and our communities in rural Maryland for the current project involves Southern Maryland, which is Charles and Saint Mary's County, where there are dramatic differences in wealth on one side of the street and abject policy, no running water, no Internet no broadband poor infrastructure for transportation and doesn't exist, as well as no broadband.

Prior to our Southern Maryland experience, which is what we're building the relationships to address the need for decentralized clinical trials, is the experience that we've had with the rural Eastern Shore, which is a ninecounty region with varying levels of poverty and wealth also, and we established a decentralized clinical trial office, which is still in existence for oncology trials in 1994, and it still exists.

The main initiating activity to make that a success was a clinician leader on the Eastern Shore, Dr. Mary De Shields. She was an oncologist. I brought in the research dollars to set up the infrastructure for the nurse CRA and the data collection system, and we had a multipronged approach, intensive community education on the benefits of clinical trials, and the public drove the establishment of that clinical trial office with their clinicians by saying, "Why don't you talk to me about clinical trials? I would have gone into it." And this is largely with primary care.

We use the AHEC on the Eastern Shore to do the continuing education that the local clinicians asked us for, to figure out what protocols are open and how to refer their patients, and again, the infrastructure building, which came from a lot of NIH funding that made it successful.

So we're ready to replicate that model. In Southern Maryland, the leadership clinician is a health officer for Charles County, and their faith-based leaders are also ready to take action. So we're happy to have this opportunity to meet with you to learn how we can interact with you to make that goal a reality for Southern Maryland.

DR. KIPP: Good morning. My name is Billie Jo Kipp. I'm a member of the Blackfeet tribe from Montana, and I'm also a Native American clinical psychologist. I've practiced for a number of years, and now have gone into administration and research, and I represent the Indigenous Innovators Collaborative.

I would like to help develop, or work with, or even plan how the value of tribal colleges, which are in tribal communities, which are rural, can be a huge part of decentralized clinical trials, just a huge part. We have the systems there. We have a lot of mechanisms there. And I want to say, too, just briefly, that one of the things that COVID has taught the tribes is how to take care of their health care when they've shut the borders of their reservations.

I've seen things pop up, like there were people putting together hospital beds to bring to people who need care in home for maybe death, and dying, and those things. Those were out of survivance. Where can clinical trials help tribal colleges, tribal communities, not be in survivance, but be a part of the answer to the disease? And we're not there, and that's where preliminary data from our work our folks in our tribal community say we want to know more. We want to know more. We don't know enough. We want to be a part of. If my aunt had access to this, maybe she'd be alive.

So those are the big things that were often left out of the equation, and I'm here to really say, how can we be part of the solution? Thank you very much.

MS. ABBADI: Hilary?

DR. MARSTON: No, you're just fine, and I think you guys have heard enough for me.

Hilary Marston, Chief Medical Officer. The only other thing I'll add is I oversee our Office of Clinical Policy, which works on research participant protections for FDA regulated research. So one of the things I would love to hear more about, whether it's today or another time, is how to make informed consent informative, but also fit for purpose for these sorts of trials in the communities that you serve. Thanks.

DR. LEE: Actually, Hilary, just to let you know, that's actually going to be our next roundtable discussion. It was confirmed, yes. That has been a topic that has been brought up by our REACH Consortium a number of times, up to the point that we made the decision yesterday to do our next roundtable on informed consent. So we are going to invite you back, if that's ok.

Great. So we're all on the same page.

I do have to let you know that we created a bunch of questions, which then we threw out yesterday after we heard the panel discussion, so those are now in the garbage.

(Laughter.)

DR. LEE: We wanted to start off the roundtable to make it as meaningful and as intentional as possible. There are going to be five overarching topics that we're going to talk about. Just listening around the table, I think we're aligned. The first one is we're going to talk about decentralized clinical trials, so I actually asked our office to print out our guidance around decentralized clinical trials, which is on everyone's desk.

What we saw here this is topic number 1 is that within the guidance itself, the definition of "decentralized clinical trials" is some or all related activities that will occur at locations other than traditional clinical trial sites, for example, at the person's home or local healthcare facility. This may include a network of locations where trial personnel and local healthcare providers work.

The key point here that was missing from the conversation yesterday is the term, "location." Location keeps coming up. But what ended up happening yesterday during the panel was that it wasn't about just the location. Having a site within a rural community does not make that a viable site. It is not just a brick and mortar, the lights are on, the electricity is running, water is there, so that we can go into that site. What came very clear out of the panel discussion was that it was about the pre-existing relationships. The relationship is missing from the terminology that's currently within our guidance, which says decentralized clinical trials. It's not just the location; it's the relationships from the tribal colleges, the federally qualified healthcare systems.

We've often heard that, "Oh, it takes time to build relationships." I can tell you right now, you can give me 300 years, and I may not be able to build the same relationships. Very likely, I will not be able to build the same relationships as our consortium members have built today. It is not just about time; it's understanding that these are people who are part of their community, grew up in their community, and have generations of people within their community.

So I just want to set the stage with that. So the first thing we're going to be talking about is decentralized clinical trials, what's currently missing in our thinking in this space and how we can add to it. The second concept that we're going to talk about today is expanding the existing capacity of these locations and relationships in rural communities.

The third element which I think I've heard a number of people talk about, including AI, which I agree, it is driving the conversation is leveraging health technology and technologies in the way that it aligns to the community. Just having the fanciest app or mobile monitoring device does not actually create equity. In fact, what we have heard, the more technology you have, the increase in health disparities you have, so really understanding what that means to align technology with equity.

The fourth element here we're going to be talking about is sustainability. As we know, we do not want to helicopter in and helicopter out. How can we make these models sustainable? And the fifth step here, which is the most exciting one, is what are the next actionable steps? Were there synergies?

So these are the five core concepts that we will be talking about today. I'm actually going to turn it over to Dr. Hayes, Dr. Becca Hayes, to tell us a little bit about your existing infrastructure, your existing relationships, and then also tell us why you took a pay cut to become a federal qualified healthcare doc.

DR. HAYES: Alright. Thanks, Christine.

I think to answer those questions, I may start with just a little bit more of my background. I am a med peds doc by background, born and raised in West Virginia, and went to medical school, residency there after coming back from college. I was a rural health scholar as a resident. I was very focused on research. I got a master's during my residency and medical education. I was going to be a dean. I mean, this was it. That was it for me.

I met my wife, who was in Columbus at that time, originally from Iowa, at the end of residency, and was going to go fellowship, and she was like, "Umph. We've got to make some money"

(Laughter.)

DR. HAYES: "-- and we've got to move closer to my parents in Iowa." So I was like, "Fine."

So I got a job, just general internal medicine, pediatrics, and they paid some loans. I was like, "Great." I was hired at a federally qualified healthcare center on the IowaIllinois border, and that was my first job at a residency. I was like, "Okay, cool. I'll pay some loans, and then move on back into academics and do research." That's what I wanted to do.

Got there and fell in love, fell in love with the patient population. I fell in love with the mission work, everything, and I also fell in love with how quickly I could do research and QI at an FQHC. So I was publishing. I was doing things that were just quicker. We in academics, we know 17 years is the published turnaround time. FQs, it's ready for you. The impact I felt is immediate and sustainable, so I have not left, and I don't plan to in the FQ world.

So it's kind of how I jumped into this. I didn't know the acronym of FQHC for a long time while I was there. So I had an opportunity to become a chief medical officer of a large FQ in the Midwest, learned population health, learned valuebased care, contracts, and all that stuff that comes with it, my wife and I. And we now have 4 littles, and we wanted to come back East to just a larger area, a little more diverse, so we moved to Raleigh about 18 months ago, and I now work for acronyms in North Carolina like the government, too NCCHCA, North Carolina Community Health Center Association. We support the FQs in the state of North Carolina. I know Vanessa, HRSA, knows a lot about FQs, but I think emphasizing the net worth that is FQs is really important because it's taken me a long time to learn, and then I realized the opportunity there.

So federally qualified health centers serve. It's the largest network of primary care across the country and serves 30 million patients, 9 million rural residents. They're everywhere. The whole goal of an FQ is to be where there's the most need. They provide primary care, of course, but there's dental, there's vision, there's OB/GYN, and there's HIV. There's homeless, and enabling service like care management, and we do population health. So when I came to the PCA, or the Primary Care Association, I was actually in charge of the clinical branch of a clinically integrated network, or an ACO, so we're in that space as well, so FQs are just everywhere.

Specifically in North Carolina, our community and I work with Perla there are 43 FQs across the state and 90 out of 100 counties in North Carolina. The goal is to be 100. Eighty out of 100 in North Carolina are rural counties, so 80 percent of the area is rural, per definition. So that's the network that we're working with. And North Carolina, in particular, is interesting, and I'm fairly transplanted, 18 months ago. We have the mountains on the west, the beach on the right, and there's 7 hours in between, with Raleigh and Charlotte in the middle, so it's everywhere, and I've been learning that.

One of my goals now, and one of my asks because we listen as a PCA that supports. We listen. "What do you need, health center? What do you need, health center?" Interest in research has been increasing, like exponentially. They're trying to figure out what do we do next. They're being asked by thirdparty players, "Can we come to your organization and meet your patients?" So they're coming to us like, "What should we do next?" So the interest is there.

I really just want that to be one of the things I really illustrate. Two weeks ago, I got a call from Oregon because he wants to it's in a very rural, primarily African American community, and they want to bring MDMA assistive therapy to the area when it is rescheduled. They're ready. They want to be ready for that. That's the level of interest. So I think that's the best illustrator.

But I get a call from a CEO or CMO every week, every two weeks. "What can we do to be ready when this is here? How do we get involved from observational studies to be clinical trial sites?" I have one health center that has rooms ready for clinical trial sites, so they're trying to figure out who do we bring in to do this or can we do this together directly? So that's kind of my current state where we are.

Christine, what was the question I was supposed to answer?

(Laughter.)

DR. HAYES: I can go forever about FQs.

DR. LEE: No, you answered the question well.

DR. HAYES: Okay.

DR. LEE: So what I'm hearing from you, Dr. Hayes, is that you're ready. The federally qualified healthcare systems are ready. They have feds waiting. They want to participate. They trust you, for them to be calling you all the time to be involved.

It was very interesting because I spoke at Becca's event virtually a couple weeks ago, and as she's describing clinical trials, I could just see docs popping up from the audience, saying, "Pick me, pick me, pick me. I'm here. I want to participate. My free clinic wants to participate. I know how beneficial this would be for my patient." And then I came back, and I saw a bunch of thank you cards stuffed underneath my door, so that was just a wonderful experience, so thank you.

DR. HAYES: I think the secret sauce that would make the FQ world, I think, right is that we're also community governed. The boards by nature have to be 51 percent community, or consumer, or patient-led. So when I get a call from a CEO, it's not just the CEO that wants to do this maybe because they want to do it. They are governed by a communityled board, so their boss is telling them, which is the community's telling them, this is a priority for us.

So I think that's really interesting. It's just very different than anything else out there. So we know the community's in the room planning this with the FQHC, so I think that's an important part of this, too, and the readiness.

DR. CLANCY: Carolyn Clancy, VA again. That was wonderful to hear. I've always had the impression, both when I was director at AHRQ and even since then at VA, that there's what you described in North Carolina, and then there's every other state.

Now, given that you've lived in several states, what else is it at the state level that is helping this?

DR. HAYES: Well, I'll say, again biased I've only been in North Carolina a lot of this is the push to valuebased care, and North Carolina just expanded Medicaid, so we're thinking sustainability as well. I think the CEOs, if I'm a CEO, I'm thinking about diversifying my revenue sources, so I'm not just relying upon HRSA. So I think it's a lot of that as well.

Then I think the physicians are pushing for it, too, because it's another tool. You come to me, I know diabetes, we got you this. I even have a case manager helping with your social drivers of health and all these things. And then something happens that prompts the need for a clinical trial, and I don't know what to do for you. That's a problem. That's a tool in our toolbox we do not have. So I think that physicians as well are pushing it.

So I guess there are a lot of reasons, but I think a lot of it is probably nationally, but certainly North Carolina is the push to valuebased care and how do we provide all these services to patients. How do we find the time to educate and do all these things, too?

DR. LEE: Thank you so much, Becca.

I actually have Becca kicking off our third concept, which is the sustainability and payment model. She's currently writing a paper with us in this space, so she's going to bring also her insights to that, too.

I'm going to turn it over to Dean Kennedy. And, please, anyone who wants to talk, please jump in. I just have a semistructure so we have the conversation going in a direction.

But, Dean Kennedy, can you talk to me a little bit more about your HBCUs, how they're trusted members within your communities, and how that relationship is with your community?

DR. KENNEDY: Thank you.

I think that the HBCUs are located across the country in both urban and rural settings, and the communities welcome us as part of that, particularly from a health professions program and health profession school. We're always getting calls from the community to come out to interact with them and to provide services for them.

Even in our programs, we're training our students to go out and work in the community. Service is a big part of what we do and what we train them to do. It's really a requirement, even in the undergraduate programs, for them to provide service. So that's how we develop these relationships with the community, and the people really look to us for guidance. In particular, even with the COVID pandemic, our president wrote a letter to the community to encourage people to get vaccinated and to participate in clinical trials.

So HBCUs across the country are important in the community and work very well in those communities to provide services, and it would be a great place to have decentralized clinical trials. So I think that's something that's very important as we think about how we can increase the diversity in clinical trials and how we can get people to engage.

DR. LEE: Great.

Dr. Millender, I think that you portray this the best by bringing your community members actually here. Do you want to maybe talk a little bit about your connections with the communities, how you're able to build that trust, maintain that trust, and sustain that trust?

DR. MILLENDER: Sure, yes. I am a nurse scientist, and obviously, as nurses, we love the community, so we are always engaging in the community at different levels. One of the things that I've always done is always giving the community a voice to speak for themselves. So by being here as a researcher, I see this aspect of clinical trials very different than the actual community partner, who's actually living it right now every single day.

What I'm hearing more and more is the different levels of connections that we have, and I think what it is, is that I'm developing a model that works for the community that wants to be engaged in clinical trials, that wants to be heard, and that wants their voice and the culture to be heard. And I'm thinking, based on the conversation, how do you create an innovative model? Yes, you have to have a brick and mortar, but what does that look like when you are in the fields, and you are actually picking the crops, and maybe you have a 30minute break, but you want to participate? So how do we take that hybrid model to them and still have a brick and mortar?

For me, those are the things that need to become more innovative because in those rural areas, you have diverse populations, sexual gender and minorities, Latinos, immigrants, and indigenous people that might not necessarily have the latest phones, but you created an app that says, ok, you have to have this kind of bandwidth, and they don't have that. They don't have a data plan constantly. They have to buy minutes. What does that look like? And then, "Do I want to use my minutes to go into your app to be in clinical trials?"

So let's just be realistic. And I guess that's what I'm trying to understand, is how does that fit when you're trying to do clinical trials in those settings that's really hard and hot outside? Do I want to seek that outside on my 30minute break, or how can you make that more feasible for me to be able to do this and give you the information you need in order for my community to have a voice when you're analyzing that data?

So that's what I'm trying to understand as we're talking more, how to become engaged. And obviously, my community partners are here who are very capable of speaking for themselves as well.

MR. APARICIO: Hi there. Boris Aparicio, REACH community centers. I just want to echo that as well for the brick and mortar portion, but also for what I believe we alluded to at the beginning, which is the connection, to know the people who are actively in that community and who work with them. Belle Glade is the first thing that comes to mind when it comes to a rural community within our own Palm Beach community, and the accessibility alone, it's included in Palm Beach County, but routinely overlooked because everything is by the coast.

Everyone just wants to focus on the pretty waters, the beaches, and that's a beautiful aspect, but Belle Glade is part of our community, too, and accessibility and getting out there is just the first part. It's actually being able to get people out of their homes, engaging in the community, and being able to catch them in between so that we can engage and provide them with the opportunity to engage in these clinical trials.

MR. GONCALVES: Thank you. Joao Goncalves, REACH. To speak to that about the community members, they already exist. Like we've been saying, they are there and they are ready. They just need facilitation. They need training. They need skill building. In the center's experience, the GuatemalanMaya Center, there are multigenerational families that have remained with the center since its inception in the mid '80s. There are folks that have remained a part of our community and are now working at our Escuelita Maya, which is our childcare/K through 8 program that we have. We have community members that only come to our Clinica Maya, which is the directservice health clinic that we started very recently in the past few years.

For Dr. Millender's point, we do need those folks out in the fields, and they usually tend to be their kids. We can facilitate that. They are ready to do that. They are ready to help their communities. So I would say, that's what I had to say there. Thank you, everybody.

DR. LEE: Thank you so much.

Does any one of our federal partners want to jump in and add to it?

Go ahead, please, Erin.

DR. ITURRIAGA: I didn't want to interrupt you. One of the questions I have, to anyone in this room, really, is in order to do the research, you need, primarily, trained research coordinators, which often are nurses. One of our CTR centers in West Virginia, they developed ISCORE-RC, a great program, but we asked them, how are you going to retain them? Because now you've trained them, and now the big pharma's going to come take them because of the pay if you're not going to pay them; yet, they are the ones that brings in the clinical research if you have an experienced coordinator. And I don't think anybody really has an answer for that, but it's going to be an ongoing problem.

So I'm just curious, if you haven't experienced in whatever specialty you want to focus on in your clinics, how will you retain them?

DR. CLANCY: Carolyn Clancy. Just to build on that for one second, I think it's retaining them but also anticipating that they might leave. They might be in love with the area and so on and so forth, but the more research they do so it would be antiisolation and connecting them with a network of others. Having tried to help a couple of our smaller facilities who wanted to get into the research game, it's harder than you think.

DR. LEE: Right. No, these are good -- oh, sorry. Go ahead.

DR. MORALES: Dawn Morales, National Institute of Mental Health. We have historically invested, put a lot of funds, in advantaged and privileged communities in building up research infrastructure, so we can do some investment in other communities. We've been struggling at the IDeA states, Pediatric Clinical Trials Network IDeA states, by the way, are federal states that don't receive so much federal research funding, not California, not Massachusetts, I think Wyoming, and places like that.

So we discovered that we put in the investment to develop the clinical trial sets, and then we invite clinical trials to come in; that's the point. We need a project coordinator to be there, and that person had to be willing to get in their car, and drive around, and do things right to make it accessible, and it's not that easy to find that person. And we've just discovered that over time, we have to invest. We've discovered that we can find nurses who are ready to quit activeduty nursing. They've been at a VA facility that's not necessarily in a major metropolis area, and they're willing to complete that research training to become a project coordinator.

So these are the kinds of challenges that have to be addressed, but it is important for the equity purposes to realize, we have done the investment in, let's say, Boston, Massachusetts, or San Francisco, California. So just realize, if somebody acts like their pockets are a little empty, well, we've done that money. We can do a little money elsewhere.

DR. KENNEDY: Kathleen Kennedy. One of the things that we're looking at with this consortium is training the next generation of researchers in the community. We work with the community to find individuals who might be interested in learning how to coordinate projects as well, but even within our institution, the future pharmacists could be trained to do this. Pharmacies are all over, and if they could be a decentralized coordinator of some clinical research, I think that might be the way to go, to train the next generation. In the HBCUs in our REACH project, that's what we're looking at, training that next generation of individuals.

DR. KIPP: Hi. I think that when we look at research in tribal communities, that we have to understand that access to PhDs is very limited, access to MDs is very limited, but what we have is we have a rich system of tribal colleges that are educating our people, whether they be young or old. And I think when we look at clinical coordinators and research coordinators, we've got to understand that there are paraprofessional access points to research, and we've got to develop them and encourage our people to look into paraprofessional models because the tribal colleges, one of their key things is gainful employment. So when we train our own people in a paraprofessional model of research, they stay there, they're not going nowhere, and they have the relationships already with people in our community.

We did a small research study and got a NARCH grant at Blackfeet Community College when I was the tribal college president, and we looked at cortisol levels out of a little lab that we had in trauma. We had Blackfeet lined up in front of our community college. They wanted to know, how does this affect them. We found high cortisol levels.

So these things are occurring. We as investors could buttress and ramp up, if you will, what the tribal colleges are capable of, knowing that they're all in rural areas, except for a couple, and knowing that it is workforce development for our people.

I came a year ago. I was in philanthropy I don't know what I was doing there, but I was there .

(Laughter.)

DR. KIPP: -- and one of the things that they spoke of consistently is generational wealth. For tribal communities, we're poor. We're in the poorest counties. You look on the map, every poor county, the top 10, has an Indian reservation on it. Blackfeet are number 5. The Rosebud Sioux I think are number 1, so, yay. But on that respect, I think it's critically important that we're not looking for generational wealth. We're looking for generational health. Thank you.

MS. NUNES: May I say something real quickly? With our project with the FQHCs, one of our goals is to be able to train and have curriculums for our providers at federally qualified healthcare centers so they're able to speak to their patients about it, but also to community health workers, promotores de salud; because they are already in communities, they're trusted. They could be that messenger for us, but they need that training, what to say and what are clinical trials. So I just wanted to say that briefly.

DR. HALL: I'm sorry. I wanted to add a really quick thing, which is I want to underline the fact that clinical trials, that's pretty easy to train people about. Cultural competency, these trusted communities and the passion behind the value added, the health of their own families, their own communities, are not things you can train. I was a Peace Corps volunteer in West Africa. I can tell you, you can't train that, to me, to be more effective than people in Burkina Faso to serve their own people.

DR. MILLENDER: I just want to add a little bit because I think I'll go back to your question of how you train them and retain them. As a researcher, we work both in the NIH, as well as the community type of research, and I think what's different about this, as I'm seeing more and more, is that you actually start from the bottomup versus the topdown approach, where when you submit a proposal, anybody, any researcher pretty much could convince a community partner to get a letter of support, and that researcher not necessarily could be a person who's actually engaged in the community. I think that's one thing that we're seeing totally different.

Here, you actually have the community partners who are doing the work, who are now working with us to make it a research project. They are the ones who are doing this day to day. They want to do this. They're engaged. So the REACH Consortium is actually working from the bottom up and connected to the researchers. So we are the researchers, again, and we are constantly involved in community, but I'm bringing them. They're hearing it. It's not me being the middle person, but that's true communitybased engagement.

So now, what we do with them, we're working with Compass, GuatemalanMaya, and many other organizations in different projects, and continually train them to do multiple levels of research and clinical trials. It's NIH, it's a SAMHSA, it's a HRSA, whatever that looks like. So they're always funded in different projects. And guess what? Our communities have diabetes, hypertension; they have all these problems, substance use, mental health. So as they learn, they will know where to go, and they're being funded over and over and training on multiple levels, not only clinical trials but also different types of research.

So I think we have to be creative to truly go after the people who are always engaged with the community to do the work, not the other way around.

DR. LEE: I'm going to have Deb talk, and then I'll go.

DR. TAIRA: Sorry. I don't mean to jump in. I just had one more followup to that. I totally agree with that, but I also feel like the training is part of it. But what's really a part of it, I think, is what Dr. Clancy is alluding to.

We found that the support and the mentorship, if they feel like they're supported and that they have people they can talk to especially in the rural areas, it could be very isolating, and there's nobody else that knows what to do. But if you build that strong network through REACH and other funding and also, we're trying to really work at shared resources. You don't have the volume maybe at one place to have that CRA that's there, but how can we leverage everything, technology and whatever, to really share resources and have people feel supported and mentored.

DR. WARRAICH: Haider Warraich, FDA. One question I have for the REACH Consortium members, and maybe for others, is as we bring research to these communities, we really want to increase the umbrella of the sort of entities that are going to be part of this enterprise, entities that may not have done research as part of their mission, and primary care is going to be a huge, I think, instrument in helping us achieve this mission. And one of the big barriers is making the value statement or trying to convince folks who've not made research part of their mission that this is something that adds value to not just their public mission but also their financial mission.

I'd love to see how folks who've been working in these communities, with these entities, have made that case, and successfully, so that we all can serve, because you'll need to scale these if you're going to be successful.

DR. LEE: I promise we did not plant that question, but that actually leads to the next core concept that I wanted to have on our list, which is the value, the value of the training programs to not just the institution, whether it's a tribal college institution, an HBCU institution, but the value it brings to the community.

I know, Dawn, you brought up the sustainability piece. Before we turn it over to the value statement, Dr. Santiago, can you talk about your students that you see, your pharmacy students, your medical students, where they come from and where they end up?

DR. SANTIAGO: Yes, sure. Darlene Santiago from Puerto Rico. In order to be successful answering the question, I think it's important that I explain to you how Puerto Rico looks, [indiscernible] Puerto Rico. So if you look and Google Puerto Rico, you will see beautiful beaches. You will see Old San Juan. You would see the big mall, Plaza Las Americas, and our fancy one that is called Mall San Juan. It has very fancy stores. But that is not an accurate representation of the entire Puerto Rican population or island.

So Puerto Rico is divided in small municipalities, over 17 municipalities, even though we're a really small island in the Caribbean. Each municipality has a mayor, and Christine mentioned the town. Every town has a square because we were first part of the colony of Spain and now we're part of the U.S. I have to say we are a U.S. territory. We are not a state, but we are U.S. citizens. I have a U.S. passport.

(Laughter.)

DR. SANTIAGO: It's important because it's not clear for everyone, so it's important. I have to voice my population.

Going back to the towns, every town has a square. The square has the mayor's office, it has a Catholic church, and on the side, it's an evangelist church because they came there. Not all municipalities and town squares have clinics. Not all municipalities have hospitals. But do you know what each square has in every town? A community pharmacy. In that community pharmacy, the pharmacist, and the technicians, and the people that work there are from the community, and they come to San Juan to be trained either in pharmacy but also other training, as nurses and physicians. But those pharmacies, they go back to their community. They go back to that pharmacy that is on the square town or even in the mountains, and they want to serve the people that they grew up with that they know from church.

My mother the other day called me, and she was like, "Do you know that Maria, the daughter of Juana, she went to the school that you're teaching, and now she's back as a pharmacist, and she recognized me because I was her teacher in second grade." So there is a community.

So that brings it to the question that it's important that the school of pharmacy I think Dean Kennedy mentioned it, that it's important that the universities train that next generation of providers, and also we can look for innovative strategies to teach students and to train students that they could be part of the efforts of increasing the health status of their own communities. The REACH consortium in Puerto Rico is having meetings with the dean of pharmacy and also the dean of the school of medicine and nursing because, of course, we know them on trying to find ways how we can train those students, and I think that will be a great strategy.

Going back also to a comment that someone mentioned, I have a clinical research coordinator in my research team. She is a nurse. And as Casey was saying, she is an advocate. She is willing, even, to have a reduced paycheck in order to help substanceuse people in Puerto Rico. And sometimes I'm like, "I don't know if I have money to cover 100 percent of your salary,» and she>s like, «It>s fine.» She has a boyfriend, he's an engineer, he makes good money.

(Laughter.)

DR. SANTIAGO: But she's very motivated and she's very willing to just work in a flexible space, but still making changes for her community. So hopefully that will answer that question.

DR. LEE: Thank you so much for answering that question.

I want to go back to Haider's question here on the value added. This is why we had to throw out our old questions. What we have heard over the last few days is that there is so much value added to increase capacity of the institutions. We have decision makers and deans here of their organizations, of their institutions. They see the value added to increasing capacity of their current curriculum certificate program, as Dr. Kipp mentioned, like even a stackon certificate program to add on to the TCUs.

The institutions have bought in. They see the value added, not only to providing a pipeline for their existing students, but also a value to their community. I always say here, the reason why I'm here, along with the staff members here at the table from our office, it was an accident. There was no pipeline. There was no outhanded REACH, or guidance, or mentorship. We're here by accident. So I think that this is where the leaders here at this table, they're making that intentional decision to extend their capacity within their existing curriculum.

I also want to turn it over to Dr. Todd Seto to talk a little bit about how you have extended not only the capacity of the Queen's Medical Center, but increased your capacity to become best friends with the primary care docs on the islands, and then also why that was the case, and how you're working with the medical schools in Hawaii.

DR. SETO: Hi. Todd Seto from Hawaii. Yes, I think it's particular to Hawaii in the sense that there's really no monolithic native Hawaiian and Pacific Islander population, or group, or voice. It's really diverse native experiences across different islands, rural settings, separated by ocean. And the common theme that we found was the primary care physicians and the primary care providers and nurses, pharmacists are part of that team as well the best way to communicate through them, for us in Hawaii, was through the healthcare system, which is kind of odd. You don't think of that as being necessarily you think of it being kind of centralized in a whiteish tower at least, but our network and most hospital networks, and medical center networks, are very broad. We have outreach into communities. We have community health workers into the patients' homes and so on.

So we are very diverse in our healthcare system and through the physicians. That's how we reach out to our community. And maybe it's unique to Hawaii, but it's partly because of the lack of a centralized group. So for us, to reach out to our patients and to decrease inequities and help address health disparities for Native Hawaiians and Pacific Islanders, it's working with those that our community trusts. So for us, a lot of our time has been spent working with our primary care providers across the state in the rural centers, in the federally qualified health centers, which are part of our network.

In the community, hula halaus are the hula groups, and you think of hula as being you have an image of that probably, but hula is a traditional dance of Hawaii. The halau is a very organized, very tightknit community, and the Kuma Hula, the teacher, is not just a hula teacher, it's also an advisor. We work with them to rethink their role, in a way, as being health because hula was health back in the day, and that kind of dance was an expression of health and was a way to be healthy.

So we've kind of helped refashion or get back to the roots of the Kuma Hula as being a healthcare provider in some ways and reaching out through them. So our network is really trying to find the trusted partner, often the healthcare provider, which in this case, we'd extend to the Kuma Hula, but also doctors, nurses, and pharmacists.

DR. LEE: Thank you so much.

I also wanted to spend some time talking about the veteran population within your community, for example, the native communities. I know Hawaii has a high veteran population, too. Both of my inlaws are retired vets and my husband's active duty. They live in rural America. They won't leave. If I try to move them, they try to disown me. So I think it's important to have that conversation, so I'll start with you, Dr. Kipp.

DR. KIPP: Thank you, Christine.

For the tribal colleges, a big population that we serve is Native American vets because they come to the colleges to really de-escalate, to integrate into the culture, to integrate into society, but oftentimes seeking skills for jobs, or even seeking further education.

The other thing on several Indian reservations that we have is mobile veterans' clinics, too, and they usually come right to the tribal colleges. The tribal colleges in tribal communities are removed from the political system because they're at college. so their funding is different. They have to set up boards that are influenced by the tribal councils because of the need to protect the tribal college so we can educate and do what we need to do. So in that respect, the tribal colleges have a lot of latitude, if you will, to serve people, to serve people uniquely, and to develop programs. And we, of course, always go back to the tribal council, and integrate, and talk with them.

The other thing about tribal colleges and research is that all tribal colleges usually hold the IRB for that nation, so they're very versed in ethics. They're very versed in what to do. And on those IRB boards sits a cultural person, because we are going to protect our people and our culture at any cost. So I think it's really incredibly important to understand that tribal colleges serve everybody, and veterans definitely, and that it is from this integration of culture, and language, and indigenous knowledge, and that's to say, there's an executive order that if you're working in tribal communities, you will include indigenous knowledge.

Tribal colleges offer the discourse, the indigenous knowledge, and the medical model of learning. I can't say enough about the ability for tribal colleges to function and to host, if you will, opportunities around workforce development like CHRs, LPNs, and integrate clinical trials in the curriculum. Tribal colleges can develop certification programs that help our people get that certificate. And you know what? That certificate, they're probably already caring for the elder, they're probably already doing it, but we give them the certificate, and the knowledge, skills, and abilities.

So it's really important for tribal college to be integrated in any kind of research. They're developing their own research capacity. I was a tribal college president and head of the research consortium, and we developed guidelines. So the ability to infiltrate tribes, or support tribes, the tribal college network is paramount to movement of medical benefits and clinical trials.

MS. ABBADI: Go for it, Deb.

DR. TAIRA: I was just going to mention that in terms of veterans in Hawaii, there's a VA hospital, and many of our students I'm with the College of Pharmacy – Our pharmacists go through there on rotation and residency. Our medical students go through there. But one of the striking things in Hawaii, and actually the Pacific, is that a lot of veterans are scattered throughout the Pacific, not just Hawaii. And what I learned a long time ago is the VA is way ahead of everybody else in telehealth in Hawaii. So I think we could leverage that and learn more from them in how we could do that in other populations.

DR. SETO: Todd Seto from Hawaii also. We have a VA outpatient center but no VA hospital, so the VA acute care is actually embedded within the community, but the VA outpatient center is actually a beautiful building, fantastic.

To add to Deb's comment, Samoa and Guam being U.S. territories, you have strong VA units down there, and it's from Hawaii that serves there. So I think you're right; it takes advantage of the telemedicine capacity. But thinking from a research standpoint, that distance is huge, and I think the ability to think of developing clinical trial capacity, embedded within telemedicine clinical capacity, I think is opportunity to elevate the care, not just in Hawaii but also down in Samoa and Guam, in particular.

DR. LEE: This leads perfectly to the third topic we're just going right along here on leveraging technology to align to the community. What I've heard from everyone here is, it isn't that technology doesn't fit; it's that most of the time we did not think about the community first, and their needs first, before aligning to technology.

I know I've talked to Dr. Hayes a number of times on that learning environment, creating that virtual learning environment, but not in the way that is one directional. We did talk about Project ECHO and thinking about leveraging that concept. I think someone else told me about this, too, about really leveraging Project ECHO to create that learning environment, that case study, and how do you get past barriers.

Dr. Hayes, do you want to maybe describe that a little bit more?

DR. HAYES: Yes, I can sure try to.

My first, I guess, orientation of the Project ECHO model was when I graduated residency, went to a federally qualified health center, and was seeing a totally different population than rural West Virginia, you can imagine. So I was able to engage for ADHD, behavioral health, and things that were outside of my trained scope and residency.

So what the Project ECHO type model allowed me was they gave me the material virtually. I learned virtually. I was also in community virtually with my peers. And I think that's the special part of a Project ECHO model, is that sustainable community when things arise, not just a 3hour curriculum and I got a certificate.

So having that mentorship and ongoing peerto-peer support, it serves really well for clinical learning, and broadening of scope, and increasing licensure type of work, so I think that's part of what we would love to see with the education in this world, too.

DR. CLANCY: So a comment and then a question. One is just to foot stomp what you've just said because I think it's hugely important. We've given Project ECHO quite a bit of funding over the years, and at AHRQ, we gave him his first grant. I just had to drop that in somewhere.

(Laughter.)

DR. CLANCY: This was a long time ago.

But really, training all kinds of people to care for hep C because at that time, way before the drugs we have now, you had to come to Albuquerque. Well, there's a whole lot of space; not quite like North Carolina, but it's a big state. But every time we get into it, what people talk about is the sense of community. Yes, they're learning something, but it's also like I've got connections now.

My question for technology was for you. To the extent that this is, in some areas, a newish thing for people, or they may have actually had bad experiences with the researchers from the big city I won't be specific here, Dawn parachuting in to say, "Do you want to be part of our project because this is required." is social media a part of this? I ask for a couple of rural VAs that got into really deep trouble that had nothing to do with research.

But social media turned out to be an issue that I had no training to deal with. I mean, people wanted me to, I don't know, prohibit stuff that was happening on Facebook and Twitter, which, really, I don't have that authority, but it spoke to me. It had a very, very, very different role than in more densely populated areas.

DR. LEE: No, that's a great call. I actually started my FDA career mining social media. But, yes, there's definitely an influence of social media. My inlaws, who both are in rural New York, Upstate New York, because of social media, they did not want to take the COVID vaccine. I tried to influence them. They told me to, like, back off, then I had to call their priest. I was like, I'm going to leverage my education of communication and have their trusted messenger be the messenger who delivers that message. So I called their priest. I got the priest on the phone with me and my husband, and we told him what was going on. He got into their home the next day; they were vaccinated the day after.

(Laughter.)

DR. LEE: I'm like, I'm not arguing with my father-in-law. He spent time in Vietnam [indiscernible].

It's like, yes, we're always going to have influences, and it's important to understand these influences. But I think the core key message we keep hearing over and over again, it is those trusted relationship sources. Obviously, I was not one to my inlaws.

MALE VOICE: [Inaudible - off mic.]

DR. LEE: Right.

But going back to technology a little bit, I know that, Ms. Perla Nunes, there were some issues with technology when you were trying to do your focus groups.

MS. NUNES: Yes. So we did focus groups with the African American communities and the Latino communities in rural North Carolina, but we were recording these focus groups. They were in person, and what kept happening was the Wi-Fi kept going out, so I had to restart. Just to keep in mind, the bandwidth in some of these areas in rural North Carolina don't exist or don't have a lot of bandwidth, so I had to keep that in mind, like, "Sorry, but we're going to have to start that all over again."

Then one of the things that came out of the focus groups with the Latino community, I did some with migrant workers, farm workers, and two of them told me they couldn't read and write, and could they still participate. And it was that empathy and that care that I gave them, like, "Don't worry about it. That's ok. It's ok. Let's talk about this."

Then the other one thing that I want to say I know it doesn't have to do with bandwidth or technology; well, I guess it does, because the theme that came out of all the focus groups we did seven is that trust is number 1, is key; and second, they wanted the information in person so that they can ask questions. And yes, they would love a pamphlet, they would love a brochure, but talk to me about it first. Let's do it in person, and then we can have that information as well.

DR. KIPP: So a couple of things I wanted to just highlight, Project ECHO. I worked for Project ECHO as a research professor in Albuquerque. What we did at the University of New Mexico is we trained community health representatives, which are your CH community health workers in tribal communities, and we did tele-training. We also gave them increased skills. We had an endocrinologist, I was a psychologist on there, and they would call in once a week, and it was casebased learning. We published an article where we decreased HbA1cs in our population, so that was huge. That was huge. So Project ECHO and telehealth is pretty phenomenal.

For tribes, when we look at the centralization of technology, it's often in the tribal college. And while we think individual learning is great and phenomenal, for native folks, we're communal people. We had a lifelong learning program for our elders to come. They learned how to get on the Internet, and then they would talk to each other. So that relationshipbased learning that tribal colleges can deliver is critical, and they have the infrastructure and technology.

As far as technology in individual homes, it's very scattered and very challenged, and I'm going to tell you a story. I like to tell stories.

When COVID happened, my granddaughter, who was in the 6th grade, was visiting me in Seattle I live in Seattle and she was getting on her class, and she got on her class, and all the students got iPads so they could still be in school. One little boy was in class, and his uncles were fighting in the background, and they were drunk, and the boy had to tell them, "Settle down. I'm in school."

Those issues, social issues, have direct implication in ability to learn. So when COVID happened and this is national, too our children came out of COVID with depression, anxiety, because their only relief from adversities was the school. Sometimes their only meal of that day was the school.

So the tribal colleges fill the gap. We're family centers learning tribal colleges. We learned long time ago, you can't just teach individuals; you have to bring in the family, so we do that. We do that using cultural ways, we do that using educational ways, we do that doing multiple ways.

I forgot to say my name Billie Kipp I think.

(Laughter.)

DR. KENNEDY: Kathleen Kennedy. One of the things that we're also doing in our training is to train our students in telehealth. We have a collaboration with the southern AHEC, where we're doing medication therapy management for those individuals in the rural community. So again, pharmacists are being trained to use telehealth to reach the rural community.

MS. ABBADI: Yes. I just had a quick comment. I think across our REACH members, we talk about leveraging existing infrastructures and relationships. And something that we've heard across our REACH Consortium is really about the importance of leveraging trusted community members; so in tribal communities as community health representatives, and federally qualified health care clinics as community health workers, and Eugenia and Casey have brought the community partners to the table.

I think someone made a comment about FDA seeming extremely farreaching sometimes, like this abstract concept, and a lot of our HHS organizations also seeming very abstract, and also the communities, vice versa, seeming a little bit abstract in concept, so really that bidirectionality.

But I wanted to talk about I always say we can't regulate people the way we do laws, and, really, the authenticity, and reliability, and the genuineness, and the responses when trusted community champions are conducting focus groups and clinical trials and I know Dr. Kipp, Dr. Parker with Tribal Nations, and also Perla with federally qualified healthcare clinics, and Darlene, when you're going out into these communities and collecting the data, what we're finding is very genuine, authentic responses from the communities that we wouldn't be able to have, or anyone, really, wouldn't be able to have without those trusted messages.

So I really want to talk about how do we leverage existing relationships and build trust? And I think trust looks a bit different in every community, and I think trust sometimes seems like an abstract concept. How do we leverage that, especially in decentralized clinical trials?

And maybe, Casey, you can talk a little bit, from a decentralized clinical trial, how do we not marginalize, further marginalize, populations when we're conducting clinical trials in a decentralized manner?

DR. HALL: My name is Casey. I remembered to say my name. I think one of the key points I would make is humancentered work with technology. We did a market session earlier this week, where we were providing some feedback on some marketing materials. My observation was a lot of those materials were really centered on the innovation, and that's great. I mean, I'm a nerd; I get it. Innovation's great, but I think the centering needs to be on the human and the added value of technology to the human experience.

I was just at an HIV and aging conference recently, where there was a lot of community representation of people living with HIV, and people are saying, "I want human connection. But that's what I want. I miss human I don't want to fill out another survey. I've been in this study for like 10 years with HIV, and I don't want to fill out one more survey; I want human connection."

I think AI has the potential to have and improved human connection through technology, potentially. I think that would be the best way to leverage AI, would be to make more humanlike interactions with the way that we do surveys. I think there's a way to leverage voice technologies and different kinds of things to make interactions more human centered. But I think with broadband issues, and talking about minoritized communities, LGBT communities, for example, are early adopters. We've used technology to create community because we were so isolated.

I grew up in a semirural area as a queer person having to create community online because I didn't have that community immediately accessible. So LGBT spaces, technology is a given. You can plug in; especially, rural LGBT folks rely on technology for a lot of things. But each community has a different way of using technology and connecting over technology.

There's existing things like WhatsApp in immigrant communities, and in Latino communities, WhatsApp is voice messaging. Lowliteracy populations use voice messaging a lot. We don't need the fanciest app because if you download the app and you try to use it, it's not going to work if you have low bandwidth, for example. But you could use apps that are downloadable and collect data passively without WiFi, but then later upload it when they do connect when they're at the pharmacy and when they do go somewhere else.

So thinking about the realities of how people use technology now, the realities of spaces that they're moving through, their activity spaces and how that impacts their technology use, and how they use it authentically and culturally in their languages, voice messages, and things like that, you need to ask the community those of us at the table who already know what that looks like to know how to leverage technology appropriately for trials.

MS. ABBADI: Eugenia, you want to add to that?

DR. MILLENDER: Just like Casey was mentioning, having these conversations, we can start thinking about, "Oh, I have this community partner that does this, and does this this way." For example, we have a lot of free clinics who target a whole different population in a primary care setting. So how do we leverage the technology they have? For example, the GuatemalanMaya Center, also they use texting with their own indigenous language to get the message across.

So if we here at this table know that we want to do a clinical trial in this thing, and now we are the connectors with that organization who knows how to do that thing well in communication and technology, bringing those two pieces together is really what makes it work and how we leverage what we already have. Now, how do you train us to be able to train them in how to make this happen? Because they're not going to spend time recreating the will and something totally different because you want to do the clinical trials. You have to make it work for us so we can make it work for you.

DR. COOPER-WILLIAMS: I just want to add to that, actually. Sorry. Jasmine Cooper, University of Maryland, Baltimore.

We had a similar experience, as Perla was saying, when we were trying to collect data in rural Southern Maryland. So what we did was we utilized the community centers that had the technology, and even then, we still had a lot of broadband issues.

So again, one of the ways that we approached it was there were folks who didn't have phones, so we used the pastors who we knew were really, really trusted, and we used the churches as spaces to collect data, and we used the community centers as a place to hold the town halls and the focus groups. And even though we were still dealing with the technology issues there, we were able to be creative and develop a workaround to still be able to reach those groups and hear their voices.

So I think, based on the space that you're trying to access in the community and trying to access what their technology abilities are and what they have access to, it's going to have to be a unique approach. We'd have to just uniquely base it on geography and what tech we have, but we can still get the job done if we are creative about how we do it.

DR. LEE: I know we're almost at time, so I do want to go to our last two points really quickly.

Dr. Hayes, can you talk a little bit about payment models and how you see that increasing capacity for your FQHCs?

DR. HAYES: Yes, I can certainly try, and we were kind of starting this conversation a little bit earlier. So when it comes to advanced payment models, to put it very simply, we're very used to fee for service. I see you for this, I bill you for this, the lab bills you for this, and everything just adds up. The incentive is to do more, to get paid more, and to bring more home.

Things are changing, if you are looking into that world a little bit, where you get a lump sum to take care of a population, so that's good. We saw that being a very good thing in COVID when things slowed down. So instead of it just relying upon me as a physician, the billable provider to sustain say the nurse or maybe the clinical research coordinator, is now you get this lump sum, and do with it as what's best for the patient, not just the billable provider. So that is a whole change in mindset, and that's valuebased care at its core.

So when we think about the definition of "value," which if you're in the payer world or everything, it's really quality over cost. You want to increase the quality and decrease the cost because then you save more, and hopefully the payer, whoever it is, is giving you some of that savings.

So when I think about that, I do think that clinical research fits right into that beautifully. It increases the quality we know that in a lot of different ways. Maybe accessibility is an easy example and decreases the cost. I mean, just think about vaccines, the COVID vaccine and how many more hospitalizations, very expensive hospitalizations, we have seen without a vaccine. So there's the cost savings. It takes a while to see that but, to me, this fits right into where we're headed with payment models as well, and that I think is the pitch to those with the ability to change what things are paid for by insurance and payment models. So I think that's maybe my take on it. I feel it naturally fits into that.

DR. LEE: That's really great.

So what we have heard is that expanding and elevating the community actually has value added not just to the patient, not just to the community, not just to the institution, but also the healthcare system. I know "APM models," "valuebased purchasing models," they're big words, but the core concept of it is actually quite simple. Are you able to manage your population health? Here are resources. And as you mentioned, Dr. Hayes, the ability to then leverage paraprofessionals, other healthcare professionals, to be part of the clinical trial process becomes an option then.

So in our last few minutes, I want to talk about next steps.

Dawn, you've already mentioned some of the next steps that you've been thinking about. Are there any areas that you see, especially from our federal government partners here at the table, synergy, you see abilities to continue the connection, abilities to explore?

DR. ROOS: This is Jason Roos. So sitting back, you sort of summarized everything that was going on in my mind here, just about the importance of the relationships and the engagements, particularly early as we're conceiving programs and as we think about technology and innovation. So it's sort of a question and a statement here.

I see a couple different areas where I'd like to see if we can engage with REACH. The first one is, in our business model, we've created a customer experience hub; so recognizing that in order for technologies to get to where they're needed, we also need to engage with the right communities for which we're targeting. We have a consortia that's centered out of Dallas, Texas. It's a hubandspoke model. The hub is in Dallas. Anyone can be a spoke. It doesn't cost anything to become part of that consortia, but it is a consortia with which we can go to engage, as we have a new program.

So Bon talked about his program. He can go into that consortia and say, "Okay. This is what

I'm trying to do. Who are the right communities that I engage with? How do I construct this program so it maximizes the reach that we're trying to achieve, the instate goals?" So that's one area. How do we connect REACH and its members into our customer experience hub? Which I think would be incredibly valuable.

The second one is a program that we have right now that is in its formative stages and we're getting ready to release a solicitation on. It's called Accelerating Clinical Trial Research, also known as ACTR. The goal of that program is to really encapsulate everything that we have been discussing here about extending the reach of clinical trials, but how do we improve the speed with which they're covered, the data, and the whole concept of decentralized clinical trials? And the intent there is for teams to come together and to offer up options and solutions as to how do we tackle some of those challenges.

So through the customer experience hub is where that information is being targeted, and you engage with the customer experience hub that has visibility of that accelerating clinical trial research or ACTR program.

Then the last one is, we're a bottomsup organization. While I'm part of the leadership team, we do not dictate the research and the programs and projects that we want to invest in. We are looking for members of the research community and members of the clinical community to come to us with ideas and the energy, and say, "Hey. This is a really tough problem. I want to come and solve it. I want to harness the resources and run with it."

So all of you around the table, please, if you have exciting ideas and interests, whether it's how do we handle the clinical trial problem or some of these really daunting challenges in your communities, we'd love to talk to folks that want to come and be program managers and really try to solve some problems. Thank you.

DR. LEE: That's a great start to this conversation. That's excellent.

DR. ROOS: [Inaudible – off mic.]

DR. LEE: Thank you.

DR. DILLON: Hi. Kristen Dillon. One thing that's coming to mind for me, relative to work that our office does, is we fund at least two grants that are planning grants. In the previous life, I have been beneficiary of one of the FORHP ones and also of a PCORI pipelinetoproposal grant. The only thing I'd say is that in rural communities, resources are often pretty thin, and we are trying to build something that doesn't exist.

So I do think there's a lot of value in understanding that there is both some time and some money needed. Usually, it's a person to help coordinate the work, sometimes renting a meeting room and sometimes buying lunch. It's not a lot of money, but I think it's too much to ask a rural community to stand up, and the ability to then be a site for a clinical trial on day one, and be ready to go with enrolling people. There needs to be a runin, and there needs to be resources to build relationships and help folks get ready to then be a site for the work.

The other thing I guess I would say is I've seen it from the other side as a steering committee chair for a practicebased research network, and in my experience there, I did not see the mechanism for the ongoing support to keep the relationships and keep the network in place. So I do think it's incumbent on the folks doing grants, that want to accomplish and use these sites, to understand that you can't turn the lights on and run a clinical trial for six months or nine months, and then magically shut everything down and have no costs, and then turn it on again six months later, and then turn it off again.

I don't know the intricacies well enough, but having some thinking about the ability to have some carryover funding or some other ways to acknowledge. It's not fair to communities to expect them to only have cost in maintaining their ability to be a site when they're actually in a project at the time.

DR. MORALES: And if I could add on to that, there needs to be a funding process in place to support that work. I'm at the NIH. We fund when the lights come on. But what about sitting down with the community and doing that deep listening and that partnership building? That does not take a week or two. It doesn't take a month or two. But who gets funded for sitting down and listening, and working on developing a relationship?

DR. CLANCY: Carolyn Clancy again. I think that's where the FDA engagement here is hugely important; because left to NIH and similar kinds of funding I'll leave ARPAH off to the side, although I will tell you I have lots of colleagues having wild fantasies. I'm holding them off for now.

(Laughter.)

DR. CLANCY: I'll just leave it at that.

When resources get tight, the big boys are going to push back. But if it says in order to get your product approved, you've got to include these components, I think that's going to be very, very powerful. I have no idea where CROs are on this, but my guess is they're less sentimental about, you know but this belongs to us. I could be wrong about that, but I think that's going to be a powerful lever.

This has been an amazing conversation, and I'm going to be following up with some of you, especially you.

DR. KIPP: Oh, thank you.

DR. CLANCY: Montana VA just got set up for research.

DR. KIPP: But Montana [inaudible – off mic.]

I just wanted to follow up on the thought of how do we get that data right away, and sitting around this table, we're on accelerated. We're accelerated all around here. So our group, the IIC group who was working with tribal colleges, we already have our data. We already have our focus group graded. We have an article ready to go out once the tribal leaders approve it. So we have the capacity, through FDA, to do a quick turnaround, engaging community in an authentic way about where do you see clinical trials. So this mechanism for us has been very, very helpful.

One final thing I want to say as a tribal college president, ARQ and NIMH, how many initiatives have been funded for tribal colleges? And I bet you'll find very few. And that's problematic because tribal colleges have the capacity to partner with university institutions, but what happens is NIH and ARPA will fund the university with a trickledown effect to the tribal colleges, when we're doing the ground work. So that kind of dogma has got to change. Billie Kipp, Blackfeet.

(Laughter.)

DR. MORALES: We do have the person who's supervising the NARCH program right over here, which is where we've inverted the funding model, and the money goes to the tribes. They're perfectly free to subcontract out whatever they like to any university or such, but your point is well taken.

DR. LEE: So I think we are a little bit over time. I have thoroughly enjoyed this conversation. I always learn something new every time. I am wondering what could be the most logical next steps. What we will be doing, actually, is we'll be following up with a transcript of the conversations that we've had today. We are intending on publishing a white paper out of this meeting. Of course, we'll be sure to clear and have everyone review the language in it, and then from that, we are hoping to take significant next steps.

Haider, do you want to maybe talk about the blueprints?

DR. WARRAICH: Absolutely.

First of all, this is a great meeting. I will say, even, part of what we've been doing is really thinking about making sure that this event is not just us all getting together and talking about what are all the barriers to being able to get more research, and better healthcare, and better health outcomes, which is the ultimate destination of this conversation, but really think about how can we turn this into action.

There are many ways that we will be exploring and advancing what we've talked about, but I think one of the ways that we do want to take everything we've learned is, really, to develop what we're for now calling "rural clinical trials innovation blueprint." I think when we think about clinical trials innovation, oftentimes we think about the highest form of technology, or the most recent, most cutting edge clinical trial design. But what we don't know and I think we've seen enough evidence is that may actually not work in many of the communities that you all represent.

So there really is a need to think about how we can actually develop a blueprint that folks can use, that researchers, industry and others can look at as they think about how do we design a trial that is representative of rural and tribal communities. So that's going to be one thing that we are going to be working on.

I would certainly encourage you all to reach out to many of the federal partners we have. The government has resources that they would like to invest in your communities, and I think that the REACH Consortium would be a great partner in advancing those proposals as well. And then there are other things that I can't talk about now, but hopefully as we work on the white paper, I think that will provide a foundation for what additional next steps you could pursue, not just at FDA, but across HHS. Thank you.

DR. LEE: Well, thank you so much, especially to our REACH members and federal partners, for being here today. I always say my goal is to never end with a word cloud, so I think we achieved that today. There are definitely next steps, the very good ideas that have come out of this.

We would like to take a picture with everyone, if that's ok. Could we take a quick picture outside?

(Whereupon, at 1:09 p.m., the meeting was concluded.)