

AstraZeneca Podcast - Episode 10

00;00;00;00 - 00;00;27;00

Brendan

Welcome back to That's understandable. Where we break down the complexities of health care and science, making them a bit more, well, understandable. I'm your host, Brendan McEvoy, US head of external communications at AstraZeneca. We are excited to be back after our winter break. Thanks for tuning back in. Don't forget, if you have been enjoying this podcast, please take a moment to like and follow it on your favorite streaming service.

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If you know someone who is interested in today's topic, be sure to share. Let's help make health care more understandable for everyone. Clinical trials are a critical component to the research and development of medicines and other medical treatments and interventions. People volunteer to take part in clinical trials to evaluate the effectiveness and safety of medicines and other medical interventions and treatments as feature options to help people prevent or treat a condition.

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When looking at who may participate in a clinical trial, we need to remember that truly it could be anyone, anybody who needs the medicine or treatment in development from any background, culture, language, race or ethnicity, socio economic status, age, gender, sexual orientation, the list goes on. Two people may have the same disease, but experience it vastly differently based on a number of factors.

00;01;23;05 - 00;01;49;11

Furthermore, we know that 20% of drugs, efficacy and effects are influenced by patients ethnic makeup. To keep in line with the vast diversity of the potential patient population, it's important that those participating in clinical trials reflect the same diversity. Unfortunately, the reality is that clinical trial participants have long failed to reflect the diversity and the ultimate patient population.

00;01;49;13 - 00;02;21;17

The United States Food and Drug Administration's 2020 Drug Trial Snapshot Summary report reported that white Americans make up 83% of clinical trial participants, despite only making up 67% of the US population. Black Americans make up 5% of clinical trial participants, and Hispanic and Latin X Americans account for less than 1% of trial participants. The topic of diversity among clinical trial participants is increasingly being discussed within the healthcare community, as it should be.

00;02;21;19 - 00;02;54;05

We need to talk about it to remedy it in 2022. The FDA proposed guidance for the pharmaceutical industry around improving enrollment of participants, identifying as being from underrepresented racial and ethnic populations. To help us dive deeper into the topic of diversity among clinical trial participants. I'm happy to welcome two individuals with experience in clinical trials. Dr. Salvatore Alesci is senior vice president of the Center for Clinical and Social Research at the National Minority Quality Form.

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Brendan

He is a position scientist and health care executive with more than two decades of working, experiencing period spanning multiple leadership roles in the government research and biopharmaceutical sectors. With a track record of groundbreaking work in medical research, health policy and patient advocacy, Dr. Alesci had made a personal and professional priority throughout his career to drive and advocate for more inclusiveness and participation in clinical trials as a way to promote health equity.

00;03;21;13 - 00;03;50;20

He has provided expert advice to multiple organizations, authored more than 50 publications, and received recognition for research excellence and including two Special Access Service awards by the US Department of Health and Human Services. Also joining us is Karla, whose name we won't use for privacy purposes. Karla identifies as a black woman in her sixties. She holds a master's degree in school psychology and is the director of school based health centers for the Test Action Clinic.

00;03;50;22 - 00;04;14;06

Karla is an active community volunteer and is passionate about eliminating disparities, improving access to health care, de-stigmatizing mental illness and addressing unmet needs with underserved communities. Karla was a patient participant in the National Minority Quality Forum Clinical Trial. So we're especially excited to hear her lived experience as it relates to our topic today. Thank you so much for joining us, Dr. Lesley and Karla.

00;04;14;10 - 00;04;35;02

Welcome to. That's understandable.

Dr. Alesci

Thank you, Brendan. It's a pleasure to be here with you and Karla.

Karla

Glad to be here.

Brendan

Great. So we've got a lot to cover. So I'll jump right into the conversation and I'll start with you, Dr. Alesci, if you could just start us off. Can you ground us a bit in the understanding of how clinical trials work and how people get involved?

00;04;35;04 - 00;05;04;15

Dr. Alesci

Absolutely. Well, clinical trials are really the backbone on medical innovation, on medical advancement. They involve different stages of research, which are really aimed at evaluating if a new treatment being developed is safe and effective. People from all walks of life can participate and in fact should participate in clinical trials, offering their unique have backgrounds to inspire the research.

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Dr. Alesci

In fact, I would say that for some people, clinical trials can sometimes be the best option to address the health care problem. My years in healthcare, you know, have seen different roles have shown me the transformative power of these trials, not just in developing treatment, but also in understanding diverse health needs.

Brendan

Great. Thank you. And if I build on that a little bit more so in my intro and you reiterate it, we talked about clinical trials being for everyone.

00;05;34;07 - 00;06;09;19

So with that in mind, what is the importance of diversity among clinical trial participants? Why is this something that really the health care industry should be focusing on?

Dr. Alesci

Well, diversity in clinical trials is crucial. We talk a lot that we heard a lot about diversity. For me, this is about participation and inclusiveness, representation. It's very important based on also what I mentioned to you before, that we ensure that the results, so by our research are relevant and effective for everyone.

00;06;09;21 - 00;06;37;10

When we include a diverse group of individuals in trials. And diversity. The game has to do not just be race, and ethnicity has to do with socioeconomic status. Yes. So the we age, we really gain insight into the different response to treatments that. Let me repeat this. Sorry, let me just go back. Sure. So. Well, diversity in clinical trials is crucial.

00;06;37;16 - 00;07;19;01

It's about ensuring that the results of our research are relevant and effective for everyone independent of age, race, ethnicity, socioeconomic status. I think about diversity in terms of inclusiveness, in terms of representation and participation, where we make sure that our trial include diverse people, we gain insight into the different responses to treatment based on these different parameters. This is extremely important, particularly in a society where we see a lot of changes in the demographics in this country and so on.

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And we want to make sure again that the drugs that are tested are tested in the same population that eventually is going to get access to them. And my work, particularly again, in the science and patient advocacy, underscored the need for trials to really mirror the diversity of the population that we in the health care system aim to serve.

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Brendan

Thanks for that. I think that it really helps to make so much sense as to why it's so critical to have people from all backgrounds and demographics participate in clinical trials. I mentioned in my introduction the FDA drug trial snapshot support, something that the Center for Drug Evaluation and Research has been publishing since 2015. The insights gleaned from this report

Brendan

really show the stark reality that there's a severe lack of diversity among clinical trial participants at present.

00;08;11;17 - 00;08;37;13

From your perspective, what are some of the reasons why there is a lack of diversity?

Dr. Alesci

Yes, actually to comment on that. First of all, I want to provide also a positive outlook. I think we are doing much better. We are not where we should be yet, but we are doing much better in terms of inclusiveness. I mean, there are several factors that have really contribute to lack of inclusiveness in the trials.

00;08;37;15 - 00;09;07;20

The one that we actually heard the most is the is still remaining. Very important is the lack of trust parties among certain community in the medical field, in the medical system. Because of past injustice, I must say, remains a very important and I mean, I trust this takes long to build especially among certain communities is definitely not a the only one, the most prevalent one, especially among the youngest.

00;09;07;22 - 00;09;42;01

I think they are all the various these barriers are for some socioeconomic barriers like that in peace or create obstacles to participation in clinical trials. Trials should be more community center, community based. You should bring the trial to the patient, not the patient to the trial. But probably one of the most important one, in my opinion, is that lack of awareness about trial opportunity, either for your patient or people in general hearing about trials from their physician.

00;09;42;01 - 00;10;29;04

For example, during the normal clinical care. Clinical care and clinical research, in my opinion, should be a continuum, should not be separate. Tackling this issue require a multi-pronged approach that involves community engagement, education and policy reforms. And these are areas that I've been deeply involved in. I would probably stress one, which is education. Education has to happen not just at the community level with the potential participation, but I would just say also at the physician level, we need more community clinicians trained us why we need better training in medical schools to make physicians more culturally sensitive I would say.

00;10;29;04 - 00;10;51;14

Brendan

Yes, several of several, you know, key prongs, if you will, to the issue. But I was I'm glad to hear that you say that despite the statistics, you know, there has there's some reason to be optimistic and there has been some improvement. And hopefully with our discussion today, we can, you know, integrate a little bit closer to some more improvement and participation.

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Brendan

It feels like the perfect time to bring Karla into this conversation to hear more about her experience. So, Karla, could you share a little bit about yourself and your health journey? And in doing that, give us a little bit of background into what led you to participate in the clinical trial?

Karla

Certainly. So. I am, as you said in my introduction, a 60-ish year old woman who identifies as black or African American.

00;11;19;19 - 00;11;49;23

I work in a health care setting and my spouse also works in a health care setting. I was asked by a coworker who had been assigned as the study recruiter if I'd be interested in participating in the minority in rural coronavirus Insights study. And that study was designed to address the need for targeted vaccination efforts in minority populations.

00;11;49;25 - 00;12;23;27

Honestly, she sounded a little desperate to find volunteers, so I agreed to participate to help her out as she was a coworker. But I also felt it was important. Since I do identify as a black woman, which are two demographics that are disproportionately underrepresented in health studies and clinical trials, and I had happily received my first COVID vaccine as soon as it was available and was a believer in COVID vaccination.

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And so that's what led me to participate.

Brendan

Great. Thank you. So you're, you know, connected to the national Minority Quality Forum and participated in one of their clinical trials. Can you talk a little bit about the process, what it was like? So you had shared sort of your, you know, connection, brought the opportunity to you and you I think, you know, luckily, you know, you participated.

00;12;51;09 - 00;13;15;14

I can I can imagine sort of the desperation going back to some of the statistics, You know, what was it? What was it like? Like, what was the process and how it things sort of transpired from that initial conversation and then throughout the experience.

Karla

So it's it's been some time. But as I recall, she advised that I was going to receive an email, which I did.

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And that email included a link which took me to a survey asking me to provide some very basic demographic information. But then it also required me to complete a much longer questionnaire, which included questions about social determinants of health and other factors

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Karla

that would typically be barriers to people deciding to receive the COVID vaccine. And then I received that same survey at the six month mark.

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Participating was quite easy. It did not take an unreasonable amount of time, but of course it required access to a computer or some other device and it required some computer literacy. So there again, there were some barriers that would have eliminated other people of color or other women who would not have had access to such a device or have the computer literacy.

00;14;23;00 - 00;14;51;07

Now, because this wasn't a quote unquote, treatment protocol, I did not have doctor's appointments or any impact on my health. So this was basically seeking my opinion.

Brendan

Great. Thanks, Karla. That's that's helpful to walk us through the process. And and I appreciate you highlighting to sort of the level of access or resource that you needed in order to participate, which is something Dr. Alesci said.

00;14;51;08 - 00;15;23;25

I mean, one of the you mentioned trust sort of location or proximity and the barriers to maybe getting there versus bringing the the trial to to a participant. As you think about Karla, someone who identifies as being part of a minority community and now having been in this clinical trial as a clinical trial participant, I'm curious just your perspectives generally on the lack of diversity that persists in the area just reflections or experiences,

00;15;23;26 - 00;16;04;25

Karla

Certainly. Well, I think it's commonly known and I agree that distrust of medical and scientific professions and institutions is a significant obstacle to marginalized groups receiving effective medical care. Also, preferences and resources affect willingness to participate in trials. I think health systems also do not seriously consider that there are smaller communities within larger marginalized groups that creates barriers to inclusion.

00;16;04;25 - 00;17;00;25

And so I think that much more serious consideration needs to be given to rural black communities versus urban black communities, working women versus stay at home mothers. Our ideologies will likely be different, and so we need to break down those larger populations into smaller and smaller communities to understand how philosophies, ideology and belief systems differ.

Brendan

That yeah, that's extremely helpful because really think about it's almost like the importance of getting a little bit inside the head of a potential participant.

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Right? And to your point, regardless of what your background is, you have to really think about who it is that you're trying to engage in in the trial. Dr. Alesci, you mentioned, you know, sort of several barriers upfront, such as trust in education, lack of resources, location. Are there any other things that you would sort of build on or add to the conversation or on top of what Karla shared?

00;17;29;17 - 00;17;53;05

Dr. Alesci

Yeah. Well, first of all, thanks, Karla, for eloquently and also in a very simple way outlined some of this issue. And your perspective is very important as a participant. Maybe I'm going to build a little bit on a few things that I point out and also mentioned some that I did. And I go back to that issue of education, there has to be bi directional.

00;17;53;06 - 00;18;23;12

Education is also education that translate into engagement. Again, I can't stress enough that for me this is a two way relation. It's about participatory health. The other thing that I would add to that is that that partnership, partnership between community leaders as well as community physicians, I think it's essential. I'm going to talk perhaps in a moment about some initiative we are launching or we have been developing a D.N.A..

00;18;23;14 - 00;18;58;27

So you have to build trust to the community directly through outreach. But also build on the trust that the community already has, either with community, church, community entities, community leaders, the churches, the barbershops, and community clinicians. I think I cannot stress enough the role of the community clinicians and the community clinics. Again, you as a patient, no matter where you are, shouldn't be asked to go to your physician for clinical care and then go to someone else maybe miles away for clinical research.

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You should all be done. You should all happen within the community. And of course, some of this take like a cohesive, coordinated partnership. Some of these also require funding, support and policy reform. One thing that I think it's missing, it's really a national, if you will, a centralized clinical trial infrastructure that takes all of this into account. Decentralized.

00;19;29;16 - 00;19;56;14

We are moving to that direction. Again, I can comment on this shortly. I want to take too much last word in your question, but I think my experience has been both working the public sector in the private sector, that the importance of collaborative efforts between healthcare provider, policy maker and communities with, you know, some short term goals but also a long term horizon is crucial.

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Brendan

Thanks, Dr. Alesci. It's helpful to hear some of the solutions identified, whether it be partnerships, policy reform. That community element, it's sort of like this thread of collaboration. And I'm getting a sense of it's really it's not a sort of it can't be solved by any one particular party organization. It's going to take a collective effort, I think, or, you know, as we think about the health care industry largely and obviously that encompasses, you know, a lot of different, you know, organizations, nonprofits, health care systems, pharmaceuticals, other manufacturers.

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When you think about that industry, what is it that you think what what role can they play? Can the industry play to help progress some of the solutions that you've identified?

Dr. Alesci

Well, I go back to where I was a few minutes ago. I first of all, I'm an optimist by nature, but my optimism is also informed by some major changes that I've seen.

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You mentioned before some of the changes at the policy level with the FDA now demanding diversity plans and so on. But I would just say that there's been increasing attention. I've witnessed myself in previous role by the pharmaceutical industry, in the academic sector as well, about about inclusiveness in clinical trials. I think there are much more resources allocated to that in many organizations now with chief diversity officers, they have like Department, they're really focusing into that.

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But to be honest with you, I think that we're I've seeing these being addressed more successfully have been in a couple of ways. Right. Why is our company that have truly adopted the concept of inclusiveness and embedded in the fabric of their culture, getting their employ time off, for example, to participate in clinical trials or to advocate for participation in clinical trials of companies that have starts even in their clinical development and and kind of embracing novel models with decentralized trial, with adoption, for example, of digital tools.

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They allow remote data capturing remote monitoring of patients. So just moving from what was and we heard so many times a patient center approach to even more a community center approach. So those are some of the things that I guess I've seen to some extent implementing by the industry and the association as well. I mean, for my body to put so much more resources in, try to align the members around this and make it a priority.

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Those are some of the things that come up right now in my mind based on person experience as well as based on, you know, my work on the advocacy space.

Brendan

Yeah, thanks. I was reflecting as you were speaking primarily, I was coming at the question from a, you know, what can the health care industry and the players in it do to sort of solve the problem, which what you shared some some great suggestions on.

00;23;14;14 - 00;23;38;02

I like how you also talked about it's also about what organizations can do internally. Right. So it is about creating an infrastructure. (*Absolutely*). Being focused on inclusion and encouraging, creating the space for their own employees to, you know, participate in that. So I was just I'm glad you added that extra element because it's it's both sort of inward and outward looking when we think about the players in the health care field.

00;23;38;03 - 00;24;18;29

Dr. Alesci

Absolutely. Both essentials.

Brendan

Karla, I'll turn to you now. You know, what additional suggestions would you have or actions that you think the health care industry can take to help help to solve the this this gap in clinical trial participant.

Karla

Well, I think Dr. Alesci highlighted one that cannot be overstated and and that needs to be community bank. He's absolutely right that if I get recruited by my primary care physician to participate in a clinical trial, then I want to be able to participate in that trial at my health care facility.

00;24;19;01 - 00;24;51;03

I want to be able to see my primary care provider. I want him to see me during this process, which would increase trust and would make me feel more comfortable. I don't want to get recruited. And then as he as Dr. Alecia said, Ben travel, you know, 50 miles away from my home to be with strangers. So I think that community based part of it is is absolutely essential.

00;24;51;05 - 00;25;34;08

I also think in terms of big pharma, I like most of the people and patients that I interact with. We believe that Big Pharma does not have our best interest at heart. We believe that the agenda that they have is greed and and that's just the public opinion of that. I believe that, you know, after drugs hit the market, it would be nice to have some sort of public campaign explaining how that drug got from the idea to my pharmacy.

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Who were the participants in the clinical trials? What were the processes of the clinical trials? We just hear about a new drug. And I think, you know, the general opinion is just another drug to make money. I believe if they could communicate the reason that, you know, this new blood pressure medication is going to be so effective, people would be more willing to participate in that.

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00;26;10;07 - 00;26;42;10

Karla

So transparency, I believe, is what I'm really talking about, transparency about the process, and then transparency about really what is the public benefit of another medication for a particular disease.

Brendan

Thanks to all of that. That's really helpful. You know, to actually to talk about sort of the the making of the medicine. Right. Like why from the beginning, where is there?

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What is the need that needs, you know, that needs to be filled and then all the way through to when when a medicine becomes available. To your point, like why why is that? Like, what is it? What's unique about that medicine? And that if I if I understand you correctly, I think it would help with back to sort of the awareness or the reasoning behind why we participate in clinical trials.

00;27;07;04 - 00;27;44;12

If there was more openness and transparency in the entire development process, it might. And, you know, tell me if I'm wrong, it might help sort of demystify.

Karla

Absolutely. And and also, if you don't mind, if I could add that on the few occasions that I've heard about a clinical trial or maybe, you know, there was some interest survey about a clinical trial, I received that electronically via mail out or email.

00;27;44;14 - 00;28;24;03

And I do not believe that that should be the first introduction to solicit any interest in a clinical trial. And granted, I realize you know, I don't have a solution to the problem and I don't ever like to talk about a problem without a solution. But I do believe it would go a long way if people could be recruited at first by some personal contact, which goes back to what Dr. Alesci talked about, community based.

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Dr. Alesci

Thanks. Thanks Karla. If allow me, Brendan. are your words here because actually you say you were not proposing solution by you just did that in your last word. And I want to kind of build a little bit about that. I actually may be a little bit extreme in my view, but I think that docs should be co-develop with the patient who should be co-develop with the community.

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We have this little mantra in my in my center in chief, which is research with the community. For the community. I think there's been quite some progress being made also in that sense. For example, I remember several years ago when I started there was a lot of dialog about the importance of releasing summary results to patient to participate in a clinical trial, even before this result were published.

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Dr. Alesci

Having a lay summary is extremely important and you know, most organizations now have that as a policy. It's crucial that patients that are involved and they put their time in clinical trial. I mean, early understanding of what the study was about and so on, which goes beyond the consent that unfortunately and that's a barrier, remain still a very legal document.

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So that to me has been a very important change that I've seen happen. I've seen companies maybe I should have mentioned these before, giving much more importance to programs like expanded access, compassionate use to make sure for post-trial answers, to make sure, for example, that participant that benefited from particular investigational trial without altering the regulatory process where offered the opportunity exists to the trial to post-trial access.

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I think going back then to the last element, there are a number of things that can be implemented and I see the role of the patient obligated mediators being important, I think as Karla opening up, having a point of contact that understand you, that is patient, I'm yellow from the community is very important. I mentioned before I want to mention some of the initiative and interest briefly.

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So we have several centers, but my center is working very closely with one of the other centers and in us, which is the Center for Sustainable Health Care, Quality and Equity. They've built connection on the ground, grassroots to a faith alliance network to a barbershop, and we work very closely with them to make sure that, again, that education and and translate into participation in clinical studies at the same time to address the gap.

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Then I mentioned to you, we are building we are trying to build a community center clinical trial network. We have this initiative called ARC Alliance for Representative Clinical Trial, which initially was funded through an FDA grant and DC, all based on outreach to community clinicians who are interested in becoming PI, but they don't have the time or the resources.

00;31;27;12 - 00;32;01;24

And we provide training a student free of charge at their convenience as well as resources to their community clinics. These are mostly FH QC to make sure that this community clinics get qualification as sites. We have now more than ten clinics, more than 12 investigators ready. They're qualified, ready to do clinical trial. But I should also point out that, you know, one advantage to me is you can build a new model, but then if the model is not utilized, it becomes a challenge.

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00;32;01;24 - 00;32;21;02

Dr. Alesci

And I see a little bit debt still as being a challenge from perhaps some company sponsor that want to go the traditional way because maybe they are afraid of doing study with investigators naive and and the regulatory demand. And so so any needs a little bit also in mind.

00;32;21;04 - 00;32;46;24

Brendan

Thanks. I see that sounds like great work. I understand that sounds like it's great work that's happening there and and it back to the piece this sort of like the the personal community connection by actually bringing the resource and education to the sites in the community is that art already I'll say maybe qualified that would open more I guess you know more options right.

00;32;47;02 - 00;33;16;10

Is is that the piece around which I didn't fully appreciate but it goes back to I'll to something that both you and Karla said is when you talk about the the sites where trials are happening, is it naive to say that they might be more likely like big institutes, students verses or in larger cities verse is you know those and you know, rural communities or in smaller communities?

00;33;16;10 - 00;33;47;01

Is that is that a fair assumption?

Karla

Well, I would just say that, you know, I'm coming at it from a academic perspective. You know, I'm John Q Public. That is my experience in and that is the experience of the patients that I engage with here at the clinic. We don't ever hear about clinical trials happening at any of our local or even regional locations.

00;33;47;06 - 00;34;16;28

You know, there are facilities in Baton Rouge, which is a community some miles away from us, but it is a, you know, research institution. And that's people's experiences is that these are large institutions that have, you know, national recognition that we can sometimes feel very disconnected from.

Dr. Alesci

Yeah, Yeah. I think I would maybe just comment on that and expand a little bit.

00;34;16;28 - 00;34;42;15

So first of all, don't get me wrong, large academic institution has been crucial in advancing the medical field and also the development of treatment and that should not go away. I think what perhaps is needed is some sort of better connection, better link with the community. And by the way, I've seen that happening in some institution. I've seen that happening with M.D. Anderson, where they have like some more of community center programs.

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00;34;42;17 - 00;35;10;07

Dr. Alesci

I've seen that happen in other places, but again, to me, the major disconnect there is that clinical research versus clinical care. And, you know, you can do both. You can still leverage the resources or in certain cases, you know, the technology or big academic center. But, you know, you can do that without the level of community involvement that is needed.

00;35;10;10 - 00;35;39;11

And in some cases, you have to decentralize things and and just do it that way. And I think that's where I sense we are moving but is not happening enough.

Brendan

So we've talked about upfront about, you know, be the initial I'll say the problem, you know, the lack of participation in from diverse populations in clinical chopper participation. Then we've talked about and we've talked about some of the barriers for that.

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We talked about some solutions. It's great, you know examples that like and Microsoft is doing doctor obesity that are helping to move the needle. What what if we look ahead and you know, SDS if solutions like the ones that you both have outlined are implemented, what would that impact be on this on scientific innovation and public health? What would that look like?

00;36;06;27 - 00;36;42;13

I'll start with you, Dr. Alesci.

Dr. Alesci

Well, look, I think based on everything that both Karla and ,I say it's it's unequivocal. Understand that having more inclusive participation in clinical trials can really revolutionize public health. I mean, really can drive further scientific innovation. It would improve learning. Would improve ultimately. I think what it what is the outcome not just for this population that are underrepresented currently, but for all youth come up for more diverse health solution.

00;36;42;16 - 00;37;15;22

I would also think that pragmatically it would decrease the costs of developing treatment because we know that a lot of unfortunately the delay in in bringing people to trials and again I keep saying should be trials. So people are related to delaying recruitment. And so and by the way, there does nothing to do just weed economics of the trials, but with the fact that every day that you delay a trial, that means a day delay in bringing an innovative medicine to the people that need them.

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So I think that embracing truly this can can a reach scientific understanding by providing a broader data spectrum, by providing more robust data, which ultimately should translate into improving outcomes, but also reducing risk for people that participate in clinical trial. Because like I was saying, you know, drugs of investigator you talking be a decent in this population. Now I can say I'm also very optimistic because I think that the technologies to our advantage one thing that I didn't talk about it and everyone is talking about right I, I say that is the biggest

Dr. Alesci

opportunity the biggest threat to actually improving participation in clinical trial because it's all based on what you feed to the machine

00;38;09;01 - 00;38;33;05

and what they learn and they learn bias information that's going to not really help, but it's going to worsen but also truly want to be positive. Think that I yeah, as a great offer a great opportunity in terms of filling the gaps in health disparity both in improving clinical trials but also predictive outcome in the end, decreasing risk for participants.

00;38;33;05 - 00;39;10;10

So I'm optimistic. Our already witnessed profile being part of that inclusive research. Can health of on treatment strategy, but also on health policy when it's really fully embedded again in the fabric of the different organizations.

Brendan

And what about you, Karla?

Karla

Well, I think the biggest and the desKarlable impact, which is something that Dr. Alesci has already said, was that we acquire vast biomedical knowledge about diseases that disproportionately affect marginalized groups.

00;39;10;12 - 00;40;05;01

I believe that the outcome would be absolute or very increased trust in medical institutions and research. I think that it would look like deep politicizing our national health organizations. I think it would look like having a market decline in unjust barriers to clinical trial participation in treatment. I would also point out just in terms of funding, what it would look like is, for instance, if institutions like the facility where I work, which is enough to see if we wanted to be a place of study and run a clinical trial, that we would be properly funded to do so.

00;40;05;08 - 00;40;35;05

So that if a university or a health system wanted to come in and do community based clinical trials with our patients, that we would be funded to provide the additional staff and resources needed. Just quickly, I would say that we did attempt to be a site for a clinical trial with veterans, which I thought would have been absolutely wonderful but provided no resources to do so.

00;40;35;05 - 00;41;08;04

So we had to abandon it because we didn't have the staff, we didn't have the means to get clients here, and it was abandoned. So, you know, while we can sometimes be quick to provide payment to patients that participate, which I know incentivizes them, but you have to consider the local facility as well, that is not going to be able to put up the resources to conduct that trial.

00;41;08;06 - 00;41;48;24

Brendan

Thanks, Karla. We're coming close to our time, so we've talked a lot about, you know, again, solutions our health care industry talked about maybe what that future state would like and how exciting it could be to have, you know, new new knowledge, new information, new innovation. I guess the final question and I'll I'll go to you, Dr. Alesci, is for folks that are listening to this podcast, where can they go to get more information if they're interested in learning more about or participating or potentially checking their availability or eligibility, rather, for participating in the clinical trial?

00;41;48;26 - 00;42;09;02

Dr. Alesci

Well, that's a very important question, Brandon, that you left for the end. So I would start by saying, first of all, everyone should seek information from great resources. I mean, we know that these days there's a lot of stuff on the Internet and so on. And it's important that when people go online, they try to look for information called reliable and sources.

00;42;09;02 - 00;42;35;06

Are this being a sponsor, a website, government health website. But I want to stress actually two there to me are probably the most important. One is patient advocacy group. I used to work actually for one of them. I used to be the chief science officer of Beyond Care, and that was a revealing experience coming from that angle for how important was the role of patient advocacy organization?

00;42;35;06 - 00;42;58;20

And I think that has been also another defense that I've seen in the industry working more closely with patients organization as a reliable, not source of information, but the not only source of information, but also a trusted source of information. Most patient, obviously, organization these days and registry where you can sign for free. And if you match the criteria clinical trial, they forsee that for you.

00;42;58;21 - 00;43;26;04

There are some patient, obviously organization that have even more resources as being like hotline to Karla's point. So you can hear voice instead of a computer or an email. So I think all of these are, you know, some very important way of learning about trial. The other one that I mentioned before, as in Karla pointed out as well, is your health care providers.

00;43;26;06 - 00;43;55;10

And I think there should be again, an important part of your conversation with your health care provider. Sometimes even push your health care provider if is not as informed about you and your trial patient are much more informed today. I don't see why during your and your visit is something new come up? Or maybe if you have a condition for which perhaps there is something new, you should have that dialog with your healthcare provider and the health care provided.

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00;43;55;10 - 00;44;23;19

Dr. Alesci

By the way, I'm not just only saying physician could be physician assistant, could be nurses and so on. So I think those are all the essential themes. Through all my work, I really advocate for very transparent, accessible information that ultimately is meant to empower the individual in making an decision. And by the way, that's also the other point that I want to stress, perhaps leaving at the end.

00;44;23;19 - 00;44;50;05

At the end, then decision has to be the person decision. You decide if you want or not to participate medical trial But yes, will be an informed decision. And I think that's where the challenge that we have right now is.

Brendan

Thanks, Dr. Alesci. I say that's a great point to end on useful tips and on seeking that information and and being best informed on on how to make a decision about whether or not to participate in a trial.

00;44;50;13 - 00;45;12;29

It's been a really fascinating conversation. I know we can probably continue to talk about this, but I really hope I know it's opened my eyes and I hope it will open our listeners eyes to to this topic more generally and to get curious about seeking more information. I do just want to ask for maybe a few more minutes of your time as we like to end the podcast with a quick game called Five Questions.

00;45;12;29 - 00;45;29;13

And and the reason for this is you know, this is a, you know, a lot of the topics that we talk about here, you know, are complex topics and we're trying to break them down here. But at the end of the day, you know, we're all humans, right? So we all have a variety of, you know, variety of dimensions to us.

00;45;29;13 - 00;45;48;24

And so this, I think, allows us to find a bit of commonality in all of us at the end there. So if you all indulge me, we'll do a bit of a rapid fire through these five questions, whatever comes to mind first, each each question I'll ask and then Dr. Alesci, I'll have you respond. And then and then Karla, you can respond right after it, okay?

00;45;48;26 - 00;46;15;22

Dr. Alesci

Yes,

Karla

sounds good.

Brendan

All right. First question is, what is a book you're currently reading or TV series you're currently watching?

Dr. Alesci

Well, I don't watch too much TV, Brandon, but I am reading out your next book. It's called *The Power of Food* by Bobby Bowden. And it's actually a Christmas present from my friend. It's a really fascinating book that explores the idea that we already know all the people we need to succeed in both our personal and professional life.

00;46;15;25 - 00;46;42;11

In fact, the book challenges the conventional approach of networking and emphasizes the importance of us focusing on really the relationship that we already have and matter the most to succeed.

Brendan

Great, sound like a winner. How about you, Karla?

Karla

I'm currently reading, "DEI, Deconstructed, your no nonsense guide to doing the work and doing it right by Lily Zheng, which is focusing on diversity, equity and inclusion.

00;46;42;13 - 00;47;03;16

Brendan

All right. To go once for us all to add to our our book list. Next question is, what was the best gift you ever received?

Dr. Alesci

Well, one of the best gifts I've ever received is actually a wall frame. I got it from my children and he has the words. The best gift a man can give is to be a good father.

00;47;03;19 - 00;47;39;16

A nice sign of recognition because I'm so busy all the time. So it makes me feel good about at least my parenting. But I should probably mention another one for Park Condition. This is a marble cube which I received recently from my significant other, and he has engraved the words one day at a time. I keep it on my desk and this is a very simple and powerful reminder to me to stay grounded and focus on on what happened during the day, you know, in a very fast paced and demanding world.

00;47;39;16 - 00;48;12;09

So those are probably the two that I think I can mention very important to me.

Brendan

That's a great reminder. Karla, how about you?

Karla

Yes. Well, my answer will not be quite so high brow as Dr. Alesci, I received an SUV from an employer.

Brendan / Dr. Alesci

well, goodness. I brought. It has. Wow. That's. Yeah, I have. That is that is quite the gift

00;48;12;12 - 00;48;36;08

Brendan

How about what is one thing you never leave your home without, Dr. Alesci?

Dr. Alesci

Well, I try not to leave my home without my wallet and my phone, which is good and best in my wallet. But I think I think one thing that I and I don't know if there was your question, but it's common sense. I learned that I common sense helps you a lot.

00;48;36;08 - 00;48;53;03

I keep saying all the things that I learned in my life. I just the most important one, I didn't learn and learned in the books. And I think it's something that I try at least do my best to bring with me, no matter where I go, no matter in which situations I am and is very helpful.

00;48;53;05 - 00;49;16;07

Brendan

Great, How about you, Karla?

Karla

My cell phone. My life is in my cell phone. Yeah, I think that's the case for most people. I think. Dr. Alesci, where is a place you always have wanted to visit?

Dr. Alesci

Well, I would start by saying that I've been lucky. I've been traveling quite a bit before. Personal, professional reason, but really a place.

00;49;16;07 - 00;49;37;18

It's really not a place. It's a continent that I would like to go visit more. East Africa. I've actually some African roots through my mother's side, but I've never had the opportunity to spend enough time there. I was only in South Africa briefly when I was representing the industry at the latest revision of the Declaration of Thinking, which was a fascinating experience.

00;49;37;21 - 00;49;57;18

But I would really like to spend time in maybe starting from Kenya and staffing up because my significant other is from Kenya. So she would not forgive me if I wouldn't start there.

Brendan

How about you, Karla?

Karla

I've always wanted to go to Ireland so that I could go to a proper pub.

Brendan

Oh I like that

Dr. Alesci

I thought you were going to say Italy.

00;49;57;18 - 00;50;21;07

Karla

Well, that's on the list to it. On the list.

Brendan

All right, last one. Dr. Alesci, what would you say is the ultimate comfort food?

Dr. Alesci

Well, look, we are talking about Italy. I'm Italian. Most Italian men cook. I love to cook. So, I mean, I could probably list a few, but I would just say promote ultimate comfort.

00;50;21;07 - 00;50;50;05

Food is spaghetti. Carbonara is not just about the taste. I think it's about the the way you cook it, the art of cooking. It's a very simple recipe, but there are certain things you must not go wrong using authentic one. Charlie And make sure you balance eggs and Pecorino Romano. So like I say, very simple, earthy relation, but sophisticated in terms of what it really means and for me also reminds me of home.

00;50;50;05 - 00;51;17;20

Soil has a special meaning.

Brendan

Yeah, make me hungry. How about you? How about you, Karla?

Karla

My homemade four cheese, mac and cheese.

Brendan

Yeah, that sounds like. Yeah, I think that's fantastic. I don't know if I could probably pull together a mac and cheese. It won't be as good as car that I that the carbonara is probably a bit too sophisticated for me to do tonight, but I'll see if I can work on that one.

00;51;17;22 - 00;51;42;07

Well, I mean, thank you both so much for for participating in this conversation today and of course for playing along with that that last game. This has been a really, really informative episode for me. I hope it will be for others, as well. And it was really great to hear your

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Brendan

experiences, the information that you have, and also your insights on how we can tackle or improve this issue of diversity in clinical trials.

00;51;42;07 - 00;52;14;27

Brendan

So Dr. Alesci and Karla, thank you so much again for your participation.

Dr. Alesci

Thank you, Brendan. Thanks for the opportunity. It's been great and thanks, Karla.

Karla

Thank you.

Brendan

And for all of our listeners, thank you so much for listening to. That's understandable. Until next time, be well, be healthy, be understanding.