New Directions 2022

Living with MS as a Black Person

Participating in Clinical Trials: Your Opportunity to Make a Difference

Presented by:

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and Victoria Reese, Patient Advocate (Co-Founder & President of WE ARE ILL)

Marie LeGrand:
Hello and welcome to MSAA's live webinar, Participating in Clinical Trials: Your Opportunity to Make a Difference. This webinar is part of our New Direction series, which is geared towards black and African-Americans living with MS as well as their care partners. I would like to take this opportunity to thank you for joining us this evening. I'm Marie Legrand, Senior Director of Mission Delivery and Health Equity for MSAA and your host for the program tonight.

Now, as you may know, MSAA is a national nonprofit organization dedicated to improving lives today for the entire MS community. Some of our free services include a National Helpline, we have equipment and cooling products, MRI funding, an online community, webinars and many more free programs available to people living with MS nationwide. To speak to one of our specialists. You can reach our Helpline Monday through Friday, 8:30 a.m. to 8 p.m. Eastern Time. And to learn more about MSAA's programs and services, please do visit our website at mymsaa.org or you can also give us a call. Before we begin our program. I would like to take this opportunity to thank Biogen, Genentech, and Sanofi Genzyme for making this program possible through educational funding.

Now, tonight, we are extremely grateful to have Dr. Jacqueline Rosenthal and Victoria Reese with us, who will be presenting on this topic. Dr. Rosenthal will provide us with a deeper understanding of clinical trials, including what information is needed to become more informed about them, as well as what participation entails. And Victoria, who is not only an MS advocate but also a person living with MS, will discuss some common questions and concerns around clinical trials with Dr. Rosenthal.

Now, the topics we'll discuss tonight are listed here on your screen. We have Clinical research: What it is and why it matters, Clinical trials: What they are and how they work, How to

participate in a clinical trial, How to assess the benefits and the risks of participation, as well as the regulations that are put in place to protect research participants, and then lastly, The importance of diversity in clinical trial.

Now, please note this program is for educational and informational purposes only and does not constitute as formal recommendations. Please do speak with your doctor or healthcare provider if you have any questions or concerns. Throughout tonight's program, you will have the opportunity to ask questions by typing them into the chat box. We encourage you to submit questions throughout the program, and we will do our very best to answer your questions during the Q&A portion of tonight's webinar. At the end of the program, we ask that you please complete a brief survey. Your feedback is extremely important and will help us in developing future programing and content. A link to the survey will also be included in the chat box.

Now, without further ado, I would like to introduce our speaker for the evening. Dr. Jacqueline Rosenthal is a clinical neurologist at the Andrew C. Carlos MS Institute at Shepherd Center in Atlanta, Georgia. She is a graduate of Morehouse School of Medicine and completed her neurology residency at Madigan Army Medical Center. She participates actively in clinical research and has worked with various MS committees and work groups to further MS education as well as increase awareness. Outside of patient care and clinical research activities, she enjoys spending time with her husband and her two young sons. I will now turn it over to Dr. Rosenthal. Dr. Rosenthal, welcome.

Dr. Jacqueline F. Rosenthal:

Thank you. Thank you so much, Marie. Well, I'm very happy to be here tonight to discuss with you this incredibly important topic. And I am going to actually just dive right in, maybe, if I can get the slides to work. There we go. OK, so clinical research, right? What is it exactly? Generally speaking, when we think about clinical research, we are talking about a very specific and systematic investigation into a particular question. And so this is important. We talk about different diseases, chronic disease in particular, in terms of better ways to detect, diagnose, treat and prevent disease. And when you're looking at MS, in particular, it's clinical research that has led to the discovery of all the treatments that we have available today. So it's really important from just a public health standpoint. It's what allows us to find these effective medicines and treatments that can just overall reduce the burden of disease. And again, not just MS, but all types of disease, chronic disease in particular.

So next, when we talk specifically about clinical trials, this is a specific type of clinical research. And what makes it different? The difference here is, again, individuals that choose to participate or volunteers are going to be assigned to one or more particular interventions. And when we say interventions, that could be a medication, for example. And during this talk, we'll talk about a lot of drug clinical trials involving drug treatments, because that's something we certainly consider a lot and is very important at the forefront of MS research. But there are other "interventions" as well.

So when you talk about a particular clinical question from a drug standpoint, it may be that, Hey, does this MS drug that we are studying reduce the amount of MS relapses someone has? Does it reduce the amount of MRI changes over time? But when you look at other things, for example, it may be a diet. Does this new diet change the disease course? Or it may be a new type of exercise or people walking faster. What is the outcome of that? But again, going back to these treatments, before a treatment is made available to people on a broad scale, these clinical trials are important and they're conducted to make sure that the treatment is safe, number one. And then secondly, that it does what it's supposed to do, that it works.

All right, so next, I just want to briefly go over the different phases of clinical trials. This comes up a lot, especially if anyone listening has entertained the possibility of entering into clinical research and clinical trials. We talk about these phases, and it can be a little confusing. But with Phase 1 clinical trials, this is really early on in the process. These are going to be small groups of people that are involved. So less than 100, usually, around 20-80 or so. And at this point, they're not even really looking too much at how the medication or drug or treatment works. They're looking to see how it's tolerated, what's the safe dose and what are potential side effects.

Then as you move on into Phase 2 clinical trials, here this is a little bit larger group of people, maybe a couple hundred. And they're still looking at safety, of course, but now they're starting to look at the efficacy as well. How does the medication work in terms of the outcome? How is it answering that question that those researchers have?

When you get into Phase 3 clinical trials, these are when you get into the, you know, a couple thousand or so patients and they are now still confirming its safety, but by this time there's a fairly good idea of a lot of those potential side effects and safety concerns, if any. And now they're really looking at the efficacy. Exactly how does it work on a larger scale? Phase 3 clinical trials are what typically give rise to or what are used for a drug to become FDA approved.

Phase 4 clinical trials, then, are after the drug has already been approved. And, you know, a little bit later we'll definitely talk about the importance of engaging in research and the importance of diversity in research, but as an example of a Phase 4 clinical trial, I would say that there is a particular trial going on now where there was a drug that did not, that was under investigation, that had a very low number of black MS patients. And so this particular Phase 4 clinical trial now, after the drug has been approved, is looking at that subset. So a different group of patients to really get a more complete idea of how that drug is working, and again, that group of patients. So that's an example of a Phase 4 clinical trial.

So next, who is involved in conducting a clinical trial? There are a lot of different moving parts and different organizations that are involved in planning, designing, organizing, and conducting a clinical trial. So when we talk about sponsors, this is basically who's paying for the clinical trial and this varies. It may be pharmaceutical companies. That's a very common one. Other organizations, maybe federal agencies like NIH or the VA. Sometimes people, individuals, like healthcare providers, for example, may sponsor their own clinical trial. So it varies. Regulatory authorities. So this an example of, this would be like the FDA, and their role really is just to make sure that clinical trials are run properly. Institutional Review Board. So this is very much on an institutional level. So whatever institution will be carrying out that research, there's going to be a group of individuals that make decisions about whether or not that study can be carried out. And I'll talk a little bit more about the IRB later on. And then the principal investigator and study teams. So, the principal investigator is the person that leads the clinical trial and is responsible for that clinical trial. And the study team works with that principal investigator to carry out all the tasks that are required from the clinical trial.

All right. So when we talk about the design of a clinical trial, again, there's a lot of planning that goes into it and a lot of people that contribute. So physicians contribute patients. Their patient input is important in terms of making sure that clinical trials are successful. There are also advocacy organizations and regulatory authorities. All of these people and organizations really do give their input to make sure the design of the clinical trial works.

When you talk about getting involved in a clinical trial, you are typically, generally speaking, kind of simplified, you may be placed in one of two groups. Right? So there's the investigational group, that is the group that's going to receive whatever is the experimental treatment, the one that they're investigating to see what that outcome is. How does it work? Does it answer this question that they're trying to answer? And that is compared to a control group. So the control group is going to receive either whatever is a current standard therapy. So when we're talking about MS, for example, what is another already FDA approved drug that we know works that they can compare a new drug to. Or, in some cases, they will use a placebo. So a placebo is a sham drug or kind of a bogus drug that they use for comparison sake. And so, you know, the purpose of that really is to make sure that with these two groups, when you're comparing them, that everything is identical between the two groups with the exception of that treatment. If it's an oral treatment, for example, then a placebo may be a pill as well that looks like the investigational treatment but maybe it's just a sugar pill.

OK, when you are assigned to a clinical trial or one of these groups, it's supposed to be done randomly. So when they talk about randomization that means that you are placed in one of those two groups by chance and not intentionally. So when you meet the study team, they don't say, Hey, we think you'd be a good fit for this group or that one. A lot of times it's computer based methods that are used to assign people to these groups. And then once you're in that group, oftentimes the study is blinded. So when it's blinded to the patient, that means that you, as a volunteer in this study, will not know are you receiving the experimental treatment or are you receiving the control treatment? On the flip side, the investigator, so when we talk about double blinded, that means that they don't know either. So when you're meeting with the study team, you don't know and they don't know which group you're in. And that's really important to avoid bias, because, as you can imagine, if you as a volunteer know that you're not receiving the experimental treatment, that may have implications on kind of how symptoms are reported. And on the same side, if an investigator knows that you are or are not receiving the experimental treatment, that may have implications as well, in terms of how you're treated in that study.

So when you talk about why or why not you should participate in a clinical trial. Just a few, a couple of reasons, you know. So one is to help others and make a difference. One potential benefit really is receiving study related medical monitoring. A lot of the time it is more extensive than what is received routinely. You're able to learn more about your health, potentially gain access to new treatments, and then get additional information for yourself and your caregivers.

So how is your information kept safe and how are you kept safe during this clinical trial? So there are a lot of rules and processes that are in place that have been developed over the years to ensure that safety is maintained, patient rights and welfare are all kept really at the forefront. The Informed Consent is a document that you would sign at the beginning that outlines everything about the study and when you sign that document, basically you're saying, I understand this study enough to make an informed decision about whether or not I want to participate. And that's pretty much the extent of that document. I'll talk a little bit more about the details of that document in the next slide.

There's also the Institutional Review Board. Again, I talked about that agency a little earlier. Again, this is every study, even if if it's a large study and it's done at 30 different hospitals or clinical sites, each of those sites is going to have their own institutional review board that will review that study, everything about it. They'll look at how are you recruiting patients, what are the criteria you use to either be involved or not be involved, what are the risks to the patient? So they look at everything about that study and they make a determination about whether or not

that study, they feel comfortable having that study carried out on an institutional level. And sometimes they'll say, hey, we need these changes made. Sometimes they'll say, no, we're not comfortable with this study. There's also the data monitoring committee. So this is a group, so once the study is already in process, that follows the study and will make determinations about whether or not the study can be continued, are there any modifications that need to be made, or, in some cases, should a study be canceled or halted.

So informed consent, again, this is that document, sometimes it could be a very lengthy document, that you would be given as you're considering clinical trials, clinical research, and it really goes over a description of the purpose of the research. So it's very important to know why are you doing this. What are the questions they're trying to ask. What is to be benefited from this research. It should outline every single thing that you should expect as a participant in detail. How many visits are there going to be? How long would the visits last? What are they going to do at the visits? Are you going to take a drug? Will you be taking a drug on your own at hom? How often will you take that drug? They should talk about whether or not there are any procedures involved. Are they going to be taking blood, are there MRI's, is there a questionnaire? So again, all these little details should be outlined in this document.

The protocol is a more extensive... the research protocol, really, is for the principal investigator and the study team that outlines all of their steps that they need to take. But again, the purpose and all of that and the plan of research should also be included in this Informed Consent. It should go over any and all risks or discomforts that you as a participant may encounter. It should go over the potential benefits. There should absolutely 100% be information there on who to contact if you have questions or concerns. And the the other big thing about this document is, you know, you can take this home, you can think about it, you can read it on your own, you can discuss it with family and friends. There's no reason why you would ever need to sign it right away.

And then lastly, it's important to ask questions. So these these documents should be written in a way where it's not necessarily overwhelming or hard to digest. Unfortunately, that's not always the case when they're trying to cram all of this information in a document. And so for that reason, as you're going through it, it's important to speak up and ask those questions that maybe aren't clear to you so you know exactly what you're getting into. At the end of the day, you may or may not want to participate, but at least then if you've asked your questions, it's an informed decision.

So when we talk about the benefits and risks again, so potential benefits of participating in a clinical trial are that if the new treatment works you may have had access to that treatment as one of the first people to benefit from it. Of course, you may be able to help future MS patients. And again, just dealing with that overall, trying to, you know, decrease the burden of disease. And then you can potentially receive additional expert medical care. On the other side, when we talk about clinical trials, again, early on, what's the purpose of these clinical trials, Right? To make sure drugs are safe and then make sure they do what they're supposed to do.

So the potential risks could be with regard to safety in terms of other side effects that were unexpected. Or were they side effects that were expected? And then secondly, does the drug do what it's supposed to do? Does it help? So a risk may be that that treatment does not work as good as standard treatments that are available. We know that with lot of standard treatments for MS, they work for some and not for others. And so this would be no exception. It may be that a treatment works for some people in the study, but did not work for you. The other thing is that clinical trials can be inconvenient. There is a lot of travel, extra time, it may include taking off

work, or, again, you know, trying to arrange for child care. There's all these things that have to be taken into account. And then lastly, we look at potential tests and procedures that may be required. Those also can be uncomfortable or time consuming. And so in thinking of these risks, these are all things that would, as you're discussing a clinical trial, that you really want to ask about and clarify.

So who can participate in clinical trials? So all trials are going to have inclusion and exclusion criteria. They are all different for all types of trials, but once you're interested in a trial, there is going to be some sort of screening process to make sure that you are eligible. And these are just some of the common inclusion/exclusion criteria that we see, especially as it relates to MS. So one is age. For most studies, you're going to see that there is a lower limit to the age, that you would have to be 18 or older. That is because children, or the pediatric population, is a very protected population. And so especially for new drugs, they are going to be tested in adults at least first.

There's also oftentimes an upper limit on the age as well. It ranges, I'm just going to throw out there, you know, 55, 60 sometimes for some of these medications. The reason for that is, it does not mean that once the drug is approved that it can't be used in older individuals, it's just for the purpose of the study that older individuals may be excluded because with age comes certain other medical comorbidities. And again with these clinical trials they're very intentional in trying to exclude any confounding factors that could affect the outcome of the study. And so that would be the reason why.

Gender may be one. So it's not common that we see this too much, but it may be a study that's only looking at men or women.

Type of MS is a common one. So with different treatments, they may only want to look at relapsing forms of MS. Whereas with other ones, they may only want to look at progressive forms, or all comers may be welcome.

The severity of MS is another inclusion or exclusion criteria that may be seen. So I would say the most common one here is that sometimes if their disability is beyond a certain level, that may be a reason why someone is excluded from a clinical trial.

Time since diagnosis. So here, again, everything varies, but based on the clinical trial, they may only want to look at recently diagnosed individuals, or they may want to look at people who've had it for a while and are stable.

Current MS status. So this I think of as, in clinical trials, someone who's interested, they may be looking at people who, you know, for example, the disease is not necessarily very active or they haven't had relapses for a certain period of time. Conversely, some studies want you to have had a relapse in the recent past as to show that the disease is active as that patient population is introduced for that study.

Previous treatment history is another big one we see with a lot of these medication treatment trials. Based on what you may have taken in the past, that may or may not exclude you from certain medication treatment trials.

And then lastly, other medical conditions. So based on other medical conditions that may have implications on your functional status or other things that can sometimes exclude you, just again, because they're trying to exclude anything that could confound those results.

So what would be your responsibilities as a participant should you decide to participate? So following the instructions of the study team, that means attending all of the visits and completing all of the necessary questionnaires and information requests and doing it on that very strict timeline is important, that way everyone who participates is kind of doing the same thing, and it helps to make the results more concrete and meaningful. It's also important to communicate with your study team if you've had any changes in your health status. So any new medications, that would need to be reported. Or if you've had any new health related problems, and these could be very minor, it could be that, Hey, I went to the ER because I had a migraine and they treated me, but those are details that you would want to communicate.

So again, it is 100%, I tell all patients, it's your decision about whether or not you participate in a clinical trial. And it's very important to ask all the questions that you need to until it's crystal clear. Some of the questions you may want to ask are what are your current treatment options, and really, how does that differ compared to whatever the study is looking at? You want to ask about your prognosis potentially with or without, maybe, standard options and then with the experimental options. What phase is the clinical trial, that's huge. Right? We talked about how the earlier phases are really focused more on safety, and as you progress, now they're looking more at efficacy.

How are patients assigned to the experimental group? So again, that's randomization. You want to know will you be assigned by chance or will they be placing you based on other factors? Will you be given a placebo? That's huge, right? You would want to know early on, what, if you're not in the experimental group, what would the control group treatment consist of? Short term and long term benefits, as well as risks? Who pays for the trial? What would you have to pay as a participant. I will tell you that you shouldn't have to pay for anything, really, with most clinical trials. So that would almost kind of be nine and a half times out of ten, a little bit of a red flag. Who is in charge of your care during the trial? So for example, let's say you're participating in a clinical trial at the same place where your regular doctor or neurologist is. It may be that as part of the trial you are seeing a different doctor in addition to your regular one. So that'd be something to ask about. The length of the trial. Can you drop out? The answer is yes. And then any required follow up after the trial is completed.

So misconceptions, right? One is that that Informed Consent document that they ask you to sign early on is not a contract. So you can leave a study whenever you want to and at any time, it will not affect your care. Researchers must keep your health information private during the study. And then with that placebo. So again, not all studies use placebo. The vast majority of MS treatment trials do not use placebo. We have all these 20 plus drugs that are out there right now. So there are plenty of standard options that new drugs can be compared to. And I will say an exception to that for some people are going to be in the progressive MS. As many of you know, the options for progressive MS are definitely limited. If you are going to be given a placebo, you'll be told before you participate in a clinical trial.

So diversity in our clinical trials is incredibly important. We know that people respond differently to medicines based on various factors: your age, gender, ethnicity, for example, all contribute. And so for that reason, it's vital that we have diverse patients in our clinical trials because that's what allows our researchers to ensure that the medicines are going to work for all people, not just a subset of people.

When we look at the black MS population in particular, the... I'll actually back up, not MS, if you just look at the black population, in particular, we make up about 13 to 14% of the population

and are participating in about 9% of clinical trials, and that's all clinical trials. When you look at only MS clinical trials, that number is actually a lot less. It's going to be in the 2-4, or 5% range, definitely less than 5. So there is this issue of low representation of clinical trials by black populations and across the board, not just MS. And the reasons for that are varied, but some may be limited access to healthcare and limited access to research clinics. We do know that certain minority populations, to include the black population, are not followed by a comprehensive MS center as frequently as the white counterparts. And we talk about a lot of research centers, that's where a lot of that research is being carried out.

There may be, as another reason, a lack of awareness of research opportunities. And so there are people, minority and underrepresented populations, who definitely want to participate in research. However, they're not getting that information. They're not given the information about how to participate and what that entails and how to go about doing that. There may be also a little bit of a lack of awareness of, Hey, this underrepresentation is a problem that needs to be addressed through clinical research. And I'll say on the side of the researchers, there's a lack of awareness of what are the needs of these minority, black MS populations, what are the values, what are the things that are required in order to increase engagement?

And then last but not least, you know, there's fear and mistrust that are going to deter people from participating in research. No one wants to be thought of as being an experimental guinea pig. There's concerns about safety, and a lot of that stems from mistrust in the healthcare system because of the history of what black individuals have suffered. And we have all these safeguards now that are put in place but that still doesn't necessarily erase that history. And it is difficult to just, you know, you can't just forget about it. And so that definitely has lingering effects. It highlights the importance, though, of why we need to, as a medical community, again, build trust with our patients and make sure that we are engaging in authentic relationships, and again, learning the needs of our communities and engaging in that way. Essentially, though, you know, it's all important because we need greater and more representative participation in clinical trials by black and African-Americans in particular, how we are going to ensure that these medications are working well in that population and not just in a subset of people.

All right. This slide just is showing that over the past 20 years there's been a lot of treatments that have come out, and the reason why those treatments were able to come out were because we did research that basically showed that those medications worked and that they're safe. So here's our call to action here, that volunteers are essential to clinical trials, that you can benefit yourself and others, and that representation from minorities is critical.

All right. And now just briefly here, I'm going to talk about the black MS population specifically and what we know. Again, not many people, not many in the black MS population are involved in clinical trials. This says less than 10%, but again, it's closer to that 2, 3, 4% range for a lot of our clinical trials that have led to the discovery to a lot of these medications. So what are the differences, right? So in looking at the incidence of MS or the rate of diagnosis of MS, we're seeing that it occurs more frequently in the black population compared to Caucasians, white Americans, Hispanic and Asian-Americans. And that, again, is in direct conflict with this outdated opinion that MS does not affect black people because we see that it certainly does. And black females in particular are being diagnosed in increasing numbers.

The MS experience for black MS patients is different as well. We are seeing more aggressive disease, more severe disease onset, more severe relapses, more frequent relapses and poor recoveries from an attack. We're also seeing some slight differences in age. There have been some reports of older or younger age at onset, but more recently it's looking like slightly

younger. And we're seeing higher, or I should say worse, MS related outcomes. So there have been higher rates of self-reported disability. So things like walking, stress, depression, spasticity, bladder problems, all of these things that we know commonly affect MS patients on a day to day basis and are directly related to quality of life. Less manual dexterity, more vision problems. There have been studies to suggest that in black MS patients, the rate of retinal atrophy is higher. Worse balance and coordination, which is likely a direct result of the fact that in black MS patients we're seeing more spinal cord involvement. And then increased MRI changes, so things like increased lesions seen and increased rates of atrophy.

So, I'm essentially just, you know, this is two slides saying that black people do worse with MS than white people, essentially. And I think this really gives rise to this question of why and is there something biologically, physiologic going on or are there other factors going on that need to be characterized? And so this really highlights the reason why research is so important.

So treatment, this is huge, right? If you're black and have MS, you want to know if the treatments are going to work as well for you as everyone else. And so, again, this is a limitation of a lot of the research that is out, the clinical trials that have led to the development and approval of a lot of drugs, or that the black involvement in these clinical trials is relatively lacking and black individuals are underrepresented. There was a study done in the early 2000s that did suggest that black patients did not respond as well to interferons as their white counterparts. It was a very limited study because it was very low numbers. You know, we're talking just, it was maybe 30 or so black patients compared to hundreds of white patients. And so you kind of have to take those results with a little bit of a grain of salt because you need more data to support that.

Now, since then, there have been a lot of clinical trials and a lot of questions asked about, hey, how does this drug work in the black MS community? And so oftentimes after a study has been done, they will go back to that study and try and pull out those numbers and pull out that black subset, that population, and see how it works. And the majority of the time, it looks like these medications are working the same as in the whole study population. But the numbers are so low that it makes it hard to know for sure because, again, with numbers comes power with these studies. And so having adequate numbers is crucial.

So why is it that... or what are some of the socioeconomic barriers to care that are possibly contributing? So it could be limited access to insurance and financial resources, less access to routine specialty and rehabilitative care. Again, this is the care that you are oftentimes given at comprehensive MS centers, lower health literacy and limited access to computers and online support. So these obviously don't affect everyone but what we are seeing is that it's disproportionately affecting the black community. And these are the things that people who are designing and paying for, sponsoring the clinical trials, and researchers need to take into account as they're designing these trials to make sure that we are creating an environment where there is an opportunity for more people to participate.

So questions that need to be answered, right? Why are there differences in disease severity? That's huge. And I think the majority of those who treat MS patients do think that a lot of it, the differences between the black MS community and others are going to be related to other things, these social determinants of health and these, you know, access to care and that sort of thing, rather than strictly biology. However, we need that research to back it up. We need to find out what are those differences and why. We need to look at how these differences impact the ability to accurately diagnose MS and then how these differences influence the way you as an MS patient would respond to treatment.

All right. So take home points here. So we know that the MS experience for black patients is different than those of other groups. It occurs more frequently. It tends to be associated with worse outcomes and increased disability. So adequate representation is critical to prove that our treatments work effectively, equally effectively across all groups. And then lastly, our research suggests that there are racial, ethnic and socioeconomic differences that truly need to be addressed in our future clinical trials.

Marie LeGrand:
All right. Well, thank you so much, Dr. Rosenthal, for this excellent presentation you gave us all a very nice overview of clinical trials, and you also shared some eye opening statistics surrounding them. So thank you once again. Next, I would like to bring in Victoria Reese for a brief fireside chat with Dr. Rosenthal surrounding this topic. Victoria is co-founder and president of WE ARE ILL, a patient advocacy organization with a mission to redefine what sick looks like for black women living with MS. As a black woman with MS, Victoria continuously shows up for her community and makes it her mission to bring more representation to research, advocacy and education surrounding this chronic disease. In addition to her advocacy work, Victoria has spent many years working in entertainment and advertising, curating authentic brand experience tailored to her clients needs. Please join me in welcoming Victoria. Welcome, Victoria.

Victoria Reese:
Thank you. Happy to be here.

Marie LeGrand:
I'll now turn it over to the both of you to go into the discussion portion of our presentation.

Victoria Reese:
Awesome.

Dr. Jacqueline F. Rosenthal:
Thank you. So I'll start off then. So, Victoria, I guess, you know, one thing I would like to know, especially as an MS provider, are, you know, is what are your thoughts about participating in a clinical trial? And why would you or why wouldn't you want to participate?

Victoria Reese:
Yeah, good question. So I have lots of thoughts about it, but a lot were already presented by you. And they would definitely surround the apprehension about clinical trials, something that as an organization we really try to do is, one, educate and inform, just like conversations and webinars like this, on what they are, how they work, who's all involved, and all the things like that.

But I also feel, I strongly believe and try to talk to our group about is the trust of it all. I think that before we even talk about... not before, but simultaneously, while we educate on what this is, we have to talk about the apprehension and what, like, stop and focus on that as a whole community and healthcare system and healthcare consumers. Just talk about the healing of it all. I think we know the history, so we don't have to give a history lesson on how the mistrust was created. But I just think it's so important to really talk about and talk candidly about ways to move forward from it. Because what I try to tell my community or our community is that those articles that we want to see ourselves in, that research that we want to see ourselves in, we

have to participate in that. And I think that that one thing, that key thing is what some of the conversations are missing, how we can get involved and move past the trust and realize how we can contribute to what we want to see in the community.

I would participate, I would participate. I can't lie. You know, I've got some hesitancy on my own, but I think that it's, I mean, it's the same hesitancy and apprehension that all black people have because no matter how informed I am, it's still in the back of my, the apprehension is still in the back of my mind. It's like a backbone. And I am not a doctor, medical provider or anything like that. So it is still intimidating but I would, because I am informed enough to know that that contribution is helpful, and it helped me and people coming after me. So I would participate. My questions would just be about, like, convenience and affordability, like can I find childcare? You know, what does that truly look like to participate in this particular clinical trial?

Dr. Jacqueline F. Rosenthal:

And that's a good point. And I do think that the folks who are designing these trials and sponsoring these trials need to do a better job at making it less difficult to participate. Because, you know, even when I look at the visits, these participants have to to come in for, it's a lot and not everyone is sitting at home waiting for their next clinical trial visit with nothing to do. Most people are working and they have families to take care of. It can be inconvenient. And then I think the other thing that I'll add that I didn't talk about during the talk, when we talk about the mistrust that unfortunately, yes, there is the kind of cultural, the history of everything that's happened that I think affects minority and black individuals from participating.

But there's still a lot of negative things that black people are experiencing on an individual basis that will then prevent them, let alone participating in clinical trials, but sometimes not even wanting to seek medical care. And so that is something else that I try to encourage patients, family, my own family members, that, Hey, just because there was this bad experience, you know, it's important to find your team and the medical healthcare team that you're comfortable with, that you feel comfortable with. I think that's the foundation. And once you've kind of at least, ok, I'm comfortable, I'm getting my medical care, I trust my doctor, then you can really start to delve into the research side of things.

Victoria Reese:

I'm actually glad you said that. And I just want to repeat it, or somewhat repeat it. I think that another thing that has to be addressed is... not addressed directly, but, I don't know, massage... taking care of... Cradled. I don't know the word, but you said something that really struck a chord with me, and I was talking about this recently, the healthcare system may want, as a whole, you know, may want clinical trial participation for good reasons and with good intention. However, society is still a thing. So in society, injustices and things like that are still happening. So regardless if it's happening directly related to the healthcare system, it's still happening. So we have to... not we... the healthcare system or healthcare professionals have to still be mindful of that mistrust, not even as it relates directly to the healthcare system. Just in general. This is still, like, if you are apprehensive about the healthcare system or things that have happened in the past and then you watch the news today, I'm still going to be mistrustful of the healthcare system because things that are happening. You know? So I just, I'm not saying that that should be something that stops you, but I do want to say that this is something that we all have to think about and this is something that we're all responsible for. So that is the healthcare consumer, which is the patient, and that is also the healthcare system, which is providers and everybody else. We all have to take responsibility for what's happening in society and how that trickles down to participation in clinical trials.

Dr. Jacqueline F. Rosenthal:
Yeah, absolutely. There's definitely a little bit of a disconnect there. But I think that, you know, there's avenues and talks like this are helpful. And they're also, you know, are being done for the people that are designing these clinical trials, it's just as important.

Victoria Reese:
Mm hmm. Yeah.

Dr. Jacqueline F. Rosenthal:
All right. Well, do you have any other questions for me about what are... if I was your neurologist and I'm asking you to participate in a trial, what are some questions that you may have for me?

Victoria Reese:
Yeah. So I was thinking about that. I feel like I'm very informed. So I was trying to take my informed hat off. I think the first question that I would truly want to know is, well, how does this clinical trial affect my current, you know, medication or whatever I'm doing, my current therapy. Do I take it at the same time? Like, you know, am I OK taking it? Like, does it interrupt it? I think that would be one of my first question.

Dr. Jacqueline F. Rosenthal:
And that's, yeah, and that's really important. And that information should absolutely be presented but it's sometimes, it's just in the documents and it's hard to pull out. You know, I think, you know, we've talked a lot about these drug clinical trials and for the most part, these are going to be disease modifying drugs. So the drugs that you're on to prevent your MS from progressing from, you know, you as an MS patient accruing any sort of disability. And with that, for most of these clinical trials, it means that that would be your drug, you wouldn't be on your standard therapy that maybe you were on before. And so when we talk about what you should expect or there's concerns about will this drug work for me? Whereas are you taking me off something that would work to put me on something that's not going to work? That's huge. Right? That is also why a lot of these trials now don't have a placebo, for that exact reason.

Now every every patient is different. So if you are a patient who has MS and it just responds to everything, it behaves, everything's great, then there could be potentially something to lose by going on an experimental treatment. OK? If you are someone who has MS and you have run through all the drugs that are out there, nothing is working and you're kind of stuck, then at that point, the risk/benefit ratio there changes a little bit. So sometimes we have people who do clinical trials because that is the option. At that point, it's either I'm going to do this or I'm not going to do... or there's nothing for me. We see that, unfortunately, more in the progressive subset of patients, there's one FDA approved option. And so it's not uncommon still sometimes within that group of patients to see some placebo controlled trials, because not everybody can take that one FDA approved option or maybe they tried it and it didn't work well for them. And so, in that person, there may be more to gain than potentially lose.

And so it is very... I say all that to say, it's incredibly individualized. It definitely requires an in-depth conversation with your medical provider because that's between you and he or she, that you guys have that in-depth understanding of what how is your MS behaving? What is it doing? What are your risks? Because your risks for participating in a clinical trial may be completely different from someone else's.

Victoria Reese:

Yeah. But see, I would want to know, too, OK, I can tell my doctor or let my doctor know that I'm interested in doing this, but I'm not a doctor and I don't know doctor talk. So if I'm participating in this clinical trial, it's going on for a while. I may be OK or I may not but how does the clinicians in the clinical trial, like, how do they communicate or keep communication going with my doctor? You know? Like, do they send updates? Are they in constant communication or is this just the initial conversation that they're having?

Dr. Jacqueline F. Rosenthal:

So it varies, you know. The simplest way is if your study team is also your primary, the team that's treating you, it's very convenient, in that way. Or at least within the same institution. You know, there have been times where I've had patients who are involved in clinical trials elsewhere. And it is, there's some extra steps that are required to make sure, you know, they don't want me to do my MRI, it has to be the study MRI that's done in a different state or something like that. But it's just, I mean, you do it, you get the details.

At the end of the day, so the one thing I will say is, at the end of the day, no matter what type of MS you have, there's certain outcomes that we want to attain. We want to make sure your MRI, for example, is not getting worse over time. We want to make sure you're not having relapses. We want to make sure your exam is not getting worse, you're not accruing disability. And so that part doesn't change, whether you're in a clinical trial or not. And if those things are happening, then you act on it. And if that means you get pulled out of the clinical trial because they think it's not best for you, then that's what happens. And so, that's the one thing to keep in mind. And I think it also really highlights the importance of, again, having a medical team you have faith in and that you trust and that you trust to let you know of these things with may arise or else that's going to create fear and doubt and uncertainty.

Victoria Reese:

I have two questions. OK, so the first one is, so I've never actually been asked to participate in a clinical trial by my neurologist. So I'm very interested to know who knows about these things? Like what? Like is there a network of particular, like, does a neurologist, or your neurologist, have to be actually a part of this clinical trial to know about it? Or do they receive emails? Like, how do the doctors know about it in order to tell their patients?

Dr. Jacqueline F. Rosenthal:

So it's true. Depending on who your doctor is, you may or may not hear about what's going on. Again, when you're at these kind of, these big centers that carry out research, I mean, there's posters and there're signs - participate in this, do this, do this. If you're someone who is getting your care at maybe a smaller place or somewhere that's not necessarily directly involved with research, it's not going to be advertised the same way. And you know, I will say, you know, like I'll throw this out there... stem cell research was a huge thing. Right? And so that is one area where I'll say that I think across the board, a lot of people would say, hey, you may be a candidate for this research. I'm going to send you to this person to see if you can get into this research study. So that happens from time to time. But not often enough.

And so on one hand, I think that there needs to be a better job at reaching out to neurologists and MS care providers who don't normally recruit for research, to say, hey, this is out there, tell your patients about it. And so that's, again, something that's going to be on, the responsibility of people who are designing these trials and also deciding where to complete the trials. But you're absolutely right. Yeah. Not everyone has the same access to research.

Victoria Reese:
OK, all right. So this is kind of like 1-B, because I had two questions. Well, 1-B is from me to you, if I'm your patient today, in layman's terms, and we are having a black girl magic kind of appointment, and you're like, Hey girl, how are you? Obviously, after we talk important stuff, how are you doing? You know, how, if I said, can you just tell me, like, why should I participate in a clinical trial? Like, what would you say?

Dr. Jacqueline F. Rosenthal:
It would depend on the clinical trial. I have patients who will come to me and ask to be in a clinical trial and I will tell them right away, no, this isn't for you, OK? Because I'll say that the potential benefits aren't there and I think, again, that's important, right? Not everyone's going to be a good candidate for every trial. And I think it's important to have someone that's going to be upfront with you about that, whether or not you potentially benefit from a clinical trial. But again, that's clinical trials. And that is important, I think, to at least ask about. So I would commend you on that for at least for asking, because that's important and you're taking on that as a patient.

But again, that answer is going to depend on the status of your MS. What that clinical trial is looking at. The reason, though, if you were a candidate to participate, that I would say to participate, truly is going to be to increase that diversity in clinical trials, to increase the adequate representation. I, as a neurologist, want to tell my black patients about this new drug that, hey, people that look like you were also included in the trial and it worked well. And when we don't have that information, it's just kind of almost self-fulfilling prophecy where, again, it creates this chain of events. And, you know, I think that's part of trying to stop that and it's important that we prove that our medications work for everybody, not just white people with MS.

Victoria Reese:
I love that. OK, so my second question is actually, people have been commenting in the chat, and I'm not even sure if everybody can see this, but two people were asking about payment or stipend. And I know everything differs. But I can imagine, and my mind is going to run, I do play by plays in my head. OK, so everything costs money these days. When you leave the house, you spend $100 stepping outside. But I'm thinking, OK, gas money to get there, take off of work, I don't have enough PTO days, childcare, like how are people that participate in this surviving outside of even a stipend, necessarily, but like, when you calculate it all, sometimes it may not really, you know, cover the things that you lost, maybe loss of wages. So is there something in place for not maybe everyone but in clinical trials in general to help with those things?

Dr. Jacqueline F. Rosenthal:
Often times there are. Not often enough, probably. That's another problem, honestly. You know, when we talk about, you know, assistance for transportation and that sort of thing, that's something that should be offered regularly. You know, for the people that are looking at these clinical trials, there's all these rules in place and they, you know, it's like, well, you can't give, you know, obscene amounts of money because then it's undue coercion, type of deal. But to just simply reimburse someone for their time and their transportation is appropriate. And it's something that I think should be taken into account, if you are wanting to participate in a clinical trial but are not being... but are not able to because it's going to affect your quality of life, then you probably shouldn't do it, honestly, and that means that they need to do a better job in designing that clinical trial so that more people can participate. And I'll wrap up there because I know we want to move to some questions from the audience.

Marie LeGrand:

Yes, yes, yes. You know, you guys were having such a great discussion. I almost didn't want to interrupt. And I'm pretty sure that you answered a lot of the questions that our viewers have. But there are a couple that we're going to touch on. So first of all, thank you both very much again for this great discussion. Again, you brought up some great points in your discussion around clinical trials from the perspective of someone who's living with MS and as well as from an MS expert. So thank you so much for that. So now the first question for Dr. Rosenthal - How do I get more information on current clinical trials that I would be eligible to participate in? So one of the viewers was specifically interested in any clinical trials currently recruiting and focusing on myelin repair. And are there any clinical trials currently recruiting for people living with MS, who are 65 and older? And I can repeat that if you need me to.

Dr. Jacqueline F. Rosenthal:
I think I got most of it. So I can't definitively answer the age question. My suspicion would be that there is, but I can't say for certain. Well, I take that back. That's with regard to drug treatment trials. There are so many studies that look at diet and exercise and a lot of other interventions that we don't have the same strict age requirements. And so there are certainly MS studies that are recruiting over 65. In terms of how to find out about those studies, the first thing I would say is talk to your doctor about it, see what they are aware of, because they're usually going to know of studies that are, you know, at least from a, like locally, you know, what's in close proximity.

The next thing I would say is really to go to like clinicaltrials.gov. And on that website you can go in there and you can search by disease state, and you could even put in remyelination and you could also look by location, and you could filter for whether or not you have, you know, relapsing or progressive MS. And you can kind of see what's recruiting in your area too. And then I would say take that information back to your doctor and ask specific questions about that if that's not something that they were necessarily directly involved with.

Marie LeGrand:
OK, all right. Thank you. So for Victoria - So from your point of view, how would having more diverse patient populations involved in clinical trials impact how you view clinical trial results and the impact on your treatment decisions in the future? And I can also repeat that, if you need me to.

Victoria Reese:
Yeah, repeat it because I feel like it's two questions.

Marie LeGrand:
Yes. OK, so from your point of view, so we'll start off, so from your point of view, how would having more diverse populations involved in clinical trials impact how you view clinical trials?

Victoria Reese:
Um, well, as a patient I take a DMT. I am an advocate for being on a therapy and, you know, being on what works best for you. And it would just be comforting, and, like I said, in a society like today, to know that I was included in the makeup of it, or at least the monitoring of how it affects black people. I think... I don't have the stats or anything like that, but we know that MS affects, we now know that MS affects black people differently. And so there's not a one size fits all situation here. In MS, in general, we know that that's not the case, but we know that it just affects us differently. And if you do that research or hear about that, then you'll understand why it's important to know, OK, if this affects me differently, I want to know that the medication was

thoroughly researched on people that look like me so that it can be the best outcome. And I think "best outcome" is a word or phrase that we use in this community a lot. "Best outcome" - we don't always know. And I just, I would feel comforted in that. What was the second part of the question?

Marie LeGrand:
You pretty much answered it because it was how would that impact your decision on treatment?

Victoria Reese:
Oh, yeah. Yeah, that did answer it. But overall, the comfort word is, on a personal level, I'd feel more comfortable. But just as a black person, I would just feel like, I don't know, more seen. Comforted again that we're included, you know, that things... I think sometimes people say or society says things weren't built for black people, you know, but if something, if I'm considered in research, that is comforting. And it makes me happy.

Marie LeGrand:
OK, good to know. I wish we had more time, you know, because there are so many great questions that came in. But I hope that our viewers through this presentation had the opportunity to get at least most of their questions answered during the presentation and also during the fireside chat portion of our program. So thank you both so very much, again, Dr. Rosenthal and Victoria, you guys were awesome, as always. This has been such an amazing and insightful program, and you've provided our viewers with more information on this topic, which can be very difficult and challenging for many. So thank you both very much. Just real quickly, do you have any last words, if you had to just give us like one sentence what would it be if you had any last words? If not, no pressure.

Dr. Jacqueline F. Rosenthal:
I would just say ask about research, start off with the questions, and then it doesn't mean you're necessarily going to participate, but just start the dialog with your healthcare team?

Marie LeGrand:
All right. Thank you. Anything from you, Victoria?

Victoria Reese:
I would just say be the change you want to see and become an informed patient.

Marie LeGrand:
Wonderful. I think we can definitely end on those two good notes. Thank you both so much, again. This concludes the webcast. Tonight's webinar was recorded and will be made available on our website at mymsaa.org. Please visit MSAA's calendar of events for upcoming webinars. And on behalf of MSAA, we would like to once again thank you, Dr. Rosenthal and Victoria, for the great presentation.

We would also like to thank our sponsors, Biogen, Genentech, and Sanofi Genzyme, for making this program possible through educational funding. And we would also like to thank our partners at Impact Education for delivering this program. We would like to thank you all for joining us this evening. Please consider completing the brief survey, which will appear on your screen momentarily and know that we are thinking of the entire MS community and hope that you and your families continue to stay safe.

Thank you all and good night.