Michael J. Fox: This is Michael J. Fox. Thanks for listening to this podcast. Learn more about the Michael J. Fox Foundation's work and how you can help speed a cure at michaeljfox.org.

Speaker 2: In this episode, you'll hear a recap from our latest Third Thursday's webinar. Expert panelists will discuss the latest in Parkinson's research and answer audience questions about living well with the disease. We hope you find the discussion helpful.

Jimmy Choi: Hello and welcome everybody. My name is Jimmy Choi. I am an advocate. I am a world record-breaking athlete, seven-time competitor on American Ninja Warrior, and I was diagnosed with young-onset Parkinson's back in 2003. I am also a member of the Michael J. Fox Foundation's Patient Council.

Now, we're all here today because we're all looking for a breakthrough, better treatments, and of course, a cure for Parkinson's. But achieving those things means that we must depend on people to step forward and participate in research. However, the process of participation can be complex and people have a lot of questions about it. So today we're going to get into how you might find the right Parkinson's clinical trial that best matches you, your lifestyle, and if you decide to sign up, what participation in those trials might look like. This webinar was sponsored by Blue Rock Therapeutics.

Now we've got a lot to discuss today, so let me introduce our panelists. Kevin Kwok was diagnosed with Parkinson's in 2009. He is a fellow member of the Patient Council and my brother from another mother. Now, after a long career in biopharma industry, he's a research advocate and a patient advisor for Critical Path for Parkinson's. Welcome, Kevin.

Kevin Kwok: Great to be here, Jimmy.

Jimmy Choi: Next we have Dr. Stuart Isaacson, a movement disorder specialist and director of the Parkinson's and Movement Disorder Center in Boca Raton, Florida. He's also a member of the Parkinson's Study Group and an investigator on many clinical trials. Thanks for being here, Stuart.

Dr. Stuart Isaacson: Glad to be here. Wish I could be one of your brothers from another mother as well.

Jimmy Choi: Last but not least, we have Dr. Paulina Gonzalez Latapi, who is a movement disorder specialist in Northwestern University, Feinberg School of Medicine. She's also the director of the Hispanic Movement Disorders Clinic and is involved in several research trials as well. Thanks for joining us, Paulina.

Dr. Paulina Gonzalez Latapi: Very happy to be here.

Jimmy Choi: Now, I'm very active personally in participating in clinical trials, especially earlier during my journey. And now, of course, I'm also active in other ways. I was an active participant before and now I sit on advisory boards or steering

committees for clinical trials. And one of the frustrations that I keep hearing from the clinicians is how long it takes for them to find people to fill in these slots that they need to run these trials. So I'm going to start with you, Kevin. What's the value in participating in clinical trials? What has your experience been like?

Kevin Kwok: Well, like you, I've actually been enrolled since my diagnosis. For me, what I can share is that Parkinson's is often a disease where you feel like you've lost control. And for me personally, being involved in the whole clinical trial process is my way of regaining control and really taking ownership of the future of our disease.

Jimmy Choi: That's a great point because in thinking back to my own journey, one of the things that got me started on clinical trials was the feeling that I wasn't smart enough to find a cure and I couldn't fund the cure myself. I didn't have billions of dollars to fund the cure. So the next best thing that I can do to get involved and to feel like I'm a part of the process was to participate in clinical trials. So thanks for sharing that perspective. Paulina, how do you encourage your patients to think about maybe participation in clinical trials?

Dr. Paulina Gonzalez Latapi: So when I talk to my patients who have Parkinson's disease, we go over what information we learn from clinical trials and how these clinical trials are very important for us to move forward and to find answers to our question. I think it's also helpful to know that different ways in which someone can participate. I think people think about clinical trials, they think about trials where new medications are being tested, but there's a lot of different research. So going over those options is important.

Jimmy Choi: Thank you. Stuart, how do you think about participation from the perspective of someone who sets up clinical trials?

Dr. Stuart Isaacson: Well, I think we're all sort of in this together trying to get better treatments and trying to find something that can slow down this disease or stop it or reverse it. And unfortunately, we don't do that in our basements. We have to rely on pharmaceutical companies that develop molecules and then we have to see if they're safe and what the right dose is and then see if they work better than placebo. That's really phase one, phase two, phase three. And we've taken the approach at our centers to really integrate the clinical research and clinical care. So when we talk about problems that exist, we talk about non-pharmacological and wellness and exercise and nutrition. We talk about FDA-approved medications and FDA investigational medications all together. So everyone at every visit can be fully informed and make their own choices as to what options to do today and which options to ponder for tomorrow.

Jimmy Choi: Now your patients, and Paulina, your patients as well come to you and it's easy for you to encourage them and recommend them to look at clinical trials because you guys are at sites where you're heavily involved in clinical trials. So Stuart, if someone is interested in exploring these clinical trials, but the neurologists or their care team, they aren't actively involved in setting up trials or running trials, how would you advise them to work around that and actually find some clinical trials?

Dr. Stuart Isaacson: I think everybody wants to know all the options that are out there. We've tried to come out and we have centers that we've set up in California and in New York, but still it's a small part of the country. So you only have to do your own investigation. The Fox Clinical Trial Finder that's on the website, you can find trials in your area, theclinicaltrials.gov. Of course, you probably get Facebook ads as well, but you have to beware of some of those.

But really once you find a center and you can get an appointment there, we have people who fly from around the country who come in who want to be evaluated. And often there's compensation and travel that can be arranged by the companies that are sponsoring the research. So if you're interested, you can almost always find a place to be seen and to do it. The further away it is, the more difficult logistically it can become as the trials go on. But often there are places nearer. It's just a matter of trying to reach out and find these and be proactive in all respects.

Jimmy Choi: One of the things that ... I've been living with Parkinson's now for 23 years and I've seen a lot of change in the clinical trial landscape over the years. And when I was first diagnosed and I went out there and looked for clinical trials, I'll be honest, there were very little that I can find. But today when you go to a trial finder, you can see an entire list of many clinical trials that are out there. Paulina, this question is for you. There are just so many different types of studies. How might a person find one study or another that are fit for them? How are trials different and what kinds of questions should people be asking as they're thinking about how a clinical trial fits them in their particular circumstance?

Dr. Paulina Gonzalez Latapi: When I talk about this with my patients, I usually tell them there's two big buckets of clinical trials. There's the observational studies, and these are studies where we're trying to answer the question to understand better Parkinson's disease. So we wanted to understand certain symptoms better or finding certain markers in the blood or imaging findings that are associated with Parkinson's disease. So we are not testing any new medications. We are just trying to understand [inaudible 00:08:17]. And these are trials where we are actually testing new medications.

And there's different types within the interventional trials. There's very early on in the molecule or [inaudible 00:08:29] we first start with making sure that this new medication is safe and trying to ascertain which is the best dose and make sure that dose [inaudible 00:08:36] and we move on further along in the different phases to look at whether this new drug is actually treating what we want to treat. And if that's the case and a medication goes through approval, then there also continues to be a lot of safety monitoring. And within these interventional trials, some trials may use one medication versus placebo maybe testing different medications.

So I think the best thing to do is to first answer the question as the participant, do I want to be in a trial where I'm helping test out new medications or right now do I want to just start by helping answer the question of what we understand about Parkinson's disease and [inaudible 00:09:21] information about my own disease? And I think that's also where the medical team can be very important. Even if the trial is not happening at your neurologist office, these are questions you can bring

to your neurologist and it's also [inaudible 00:09:34] to contact the study team and just say, "Hey, I'm interested in this trial. Can you give me information and would I be eligible?"

Jimmy Choi: So one of the things that you're bringing up here is, first of all, I noticed a lot of questions is popping in because it makes a lot of sense because now between Stuart and yourself, you've introduced a lot of things that would raise questions like depending on what stage the clinical trials are, whether or not it's an observational study or whether or not they're testing a compound, there's just a whole bunch of variables that come in. So as a participant, I take a lot of that into consideration when it comes to deciding which trials to get involved in. So Kevin, when you're considering to be a participant in the trial, what kind of questions are you personally asking?

Kevin Kwok: I think it's like an onion. You want to start off with a very basic question. What is the question that's being asked or being studied? That's what they call the hypothesis. And once you answer that, the different layers really uncover the stage of the trial that you're looking at or the complexity of the intervention. But I think it's really important first to ask that overarching question to make sure that it jives with what your desires are.

Jimmy Choi: I think that's important, right? What your desires are translates into your life, your lifestyle, what's important to you because all of us are dealing with different various sets of challenges when it comes to living with Parkinson's. So I think that's a great start to this is asking yourself exactly what your why is, because Kevin, your why would be different than mine. So that brings me into an interesting ... When I participate in clinical trials, there's a lot of initial questions about eligibility, whether or not I would even be considered for a trial. So Paulina, what does eligibility mean and how does that help within a study? Certain criteria is created, how does that help a study? Why not just let everybody in?

Dr. Paulina Gonzalez Latapi: I mean, with these studies, we're trying to answer specific questions and it's also very important that we're trying to make sure the study is [inaudible 00:11:44], that we're actually taking into account their safety. So the way that I think about eligibility, it's not as a way to keep people out of the trial, as you mentioned earlier, we want to have as many people participate as possible, but it's a way to make sure that we are going to be able to answer the question that is being asked and also make sure that the people who are being enrolled in the study, that they are going to be safe so that we are enrolling the specific population that we want to [inaudible 00:12:16].

Jimmy Choi: Yeah, I think that's important. The two key takeaways for me is safety, making sure that we bring in the people that fits the criteria of the question that we're trying to answer because there's more emphasis in the safety levels for that particular group because that's where researchers are focused on.

Speaker 2: And now a word from our sponsor. Scientists are studying ways to replace neurons loss due to Parkinson's disease with healthy cells. BlueRock Therapeutics is recruiting volunteers for a clinical trial to test one of these

methods. To learn more about the study, check out the link in the show notes or visit expditestudy.com. That's E-X-P-D-I-T-E-S-T-U-D-Y.com.

Jimmy Choi: Stuart, I wanted to ask about randomization and placebo because when I enter a trial, usually in a later stage in their clinical trial phase, we run into placebo or actual treatment. Now, how can someone learn the likelihood that they'll actually get the intervention versus a placebo?

Dr. Stuart Isaacson: Well, most trials, 50% of people are randomized to get either the active drug or a placebo drug. Some trials are 75% to 25%. Each trial can be different. Let's say 50-50. You may not know which 50% you'd prefer to be in. It might seem first intuitive, "I want to get the active drug. I'm joining this program," but in most programs after a period of three or six months, everybody gets the active drug. It's just the first month or three months or six months where you don't know if you're getting this or that. This is a way of getting, in a sense, tomorrow's treatments today, but if you have to wait three or six months to get access to tomorrow's treatments, that might be a small price to pay, especially when we don't know and many people feel better with placebo. That's the placebo effect.

Just being in a research program often gives a lot of information, information about the tests that are done, the scales, this tapping and walking UPDRS, being involved, a lot of attention from research coordinators and clinicians. So even though it's not the active drug, placebo works and people often feel better. So I think people often feel better in both. We always see a placebo benefit in our trials and I think most people, regardless of which arm is randomized to the active drug or placebo drug, will note improvement. And then if you have access to an open label extension in three or six months, you get the drug as well.

Jimmy Choi: Just a quick question on the open label extension. When I get into a clinical trial, I personally ask the question, if I get the placebo, when will I receive ... Or if I will be able to receive the actual intervention itself? And the answer to that varies depending on the trial. Are there certain things that patients should consider when they're getting themselves into that situation?

Dr. Stuart Isaacson: Yeah, I think it's really important that sponsors, pharmaceutical companies often are committed to providing the medication to those in the early trials when it's safe to do so. And this is about safety. The FDA and the manufacturer has to know that it's safe, that enough people have tried the medication. If it's a new medication, you might say, "Well, I want to try it, but we may not know it's safe for more than six months or a year or two." So as safety grows, then we learn more. But we always try to get these manufacturers and pharmaceutical companies to agree that if it becomes available, people in the trial would be able to get it in an open label extension trial. For many trials, these open label extension trials are beginning and committed to before someone goes into a trial, but there are some trials where there either is not enough safety information to have that open label initially. So it's part of the process.

In all research programs, whether it's the randomized, whether it's early phase one or two or phase three, if it's open label extension, no one has to fear that once they say yes and are committed and enter a program, that they have to stay in it.

People can leave a research program at any time for any reason and continue to get the same clinical care they were getting beforehand. So even though a program may go on, no one has to continue. People change their minds all the time. Certainly I know I do.

Jimmy Choi: And I'll be honest, I have as well. I've gotten myself into a clinical trial that later I thought this just isn't right for me or the commitment that's being asked, it just doesn't fit my lifestyle. And that's one of the things that I appreciate about most clinical trials that I've been involved in is that once you have established eligibility, they're still very cognizant of you as the patient in terms of your treatments and your needs. So Kevin, how do you think about patient centricity when you're evaluating trials for yourself?

Kevin Kwok: Yeah. Patient centricity is a fancy word for saying, do they think about you in the design and the execution of the trial? The FDA and numerous companies are following a trend now where they're actually seeking patient input in the design of those trials. And so for me, I've been involved in a lot of these trials to kind of dissect what the study actually looks like and how onerous is it? Is it friendly? Does it take into consideration your care provider? This type of thinking is a cultural shift in the way we do clinical work. So for me, if I feel like a patient group has vetted the trial, I feel a little bit better about recommending it.

Jimmy Choi: Yeah, you're absolutely right. And just thinking back earlier on in my journey, there was definitely less feedback from the patient community or the care partner community as these trials were being designed. So that's a very important note. So thanks. I just wanted to take a moment to call out the landmark PPMI study, which is still recruiting volunteers today, the Parkinson's Physician Medicine Initiative, formerly known as the Parkinson's Progressions Markers Initiative is expanding. People from all backgrounds with and without Parkinson's can help move research forward.

Now I want to talk about patients and their families and care partners. Paulina, I'm going to turn to you and wanted to get your thoughts on how might study participation change somebody's care.

Dr. Paulina Gonzalez Latapi: The first one is that it depends on the study that you're participating. For observational trials, again, for most of them, treatment that one is getting would not ... You will just be either answering some more questions or questionnaires when you see the people in the trial. You might be seeing an additional neurologist who is one of the investigators in the trial. When it comes to interventional trials where a new medication is being tested, some of these trials might ask that people remain on a stable dose of medication for a period of time. So that's why it's important that the treating neurologists know if someone is participating in a trial.

Now that does not mean that if medication changes are necessary, then the clinical care is the most important. That might just be one consideration. We'll ask you to be on a stable dose of medication for a time. Certain trials might ask people to be off medication so that they're eligible for the trial. I'll also say that for a lot of these trials, it might also be a way for people to engage with a

different movement disorder specialist. As someone who sees a lot of research participants, some of these participants have [inaudible 00:20:16] at home and then they travel to Chicago and then they see me on a regular basis for the trial and will also ask me some questions or about what we're doing. And so it might also be a way to get some face time with another movement disorder specialist when it comes to Parkinson's disease trials.

Jimmy Choi: Yeah, I think you're absolutely right. As far as my own personal experiences have taught me is that I've never been asked to fire my movement disorder specialist and to make a complete change. I've always been encouraged to work alongside with the clinical movement disorder specialist along with my movement disorder specialist. I've never been asked to make major changes to my dose in terms of my medication. And I will add that I was involved in an observational study early on. That did change the way that I cared for myself, which it was a forced exercise observational study and it changed the way that I live for sure by adding a lot more exercise into my daily regimen. So that's how it's changed for me.

Now, Kevin, what other responsibilities or commitments might a study ask from its volunteers in your experience?

Kevin Kwok: Well, one thing, especially we're in this world of social media, I know that it's really important to preserve the unbiasedness and the integrity of the study. So they often say you shouldn't make comment or post things on Facebook or on internet, which would influence the way other people interpret their role in the trial.

Jimmy Choi: That's important and asking people not to talk about, and I'm not saying that it's necessarily like hush, hush, don't talk about it, but definitely that the influence that you can possibly have can change a person's opinion and that's very important.

So with that said, Stuart, how do you advise people balancing their hopes and expectations and also the risks of participation? I'll be honest, when I first started in clinical trials, it was a time in my life where I was a little bit desperate and I was hoping that whichever trial I signed up for was going to be the cure. But as we know today, since we still don't have a cure for Parkinson's, the trials that I participated in didn't produce a cure. So how would you advise people of balancing their hopes and expectations?

Dr. Stuart Isaacson: Well, hope is important and we hope to find better treatments. All the new medications, probably about a dozen new medications to treat Parkinson's motor and non-motor symptoms have come out of clinical trials in the past 10 or 15 years. People in those trials got them sooner. Other drugs that were tried did not result in approvals, and those were not positive.

I think you go in with an open mind. We don't want to unnecessarily make a program fail because we have too much hope or too much expectation or too little hope or too little expectation. We have to be fair. But I think it's also fair to think that when you get a prescription for a medication, old or new, before you

take it, there's fear. You wonder about side effects. You wonder if this medicine will help. You wonder if it's going to be a great medicine, you hope it will. You don't know if your expectation should be this may the best medicine I ever took or a lousy medicine that's just too difficult to take.

So I think when we prescribe medications that have been approved, it's not so different when we administer medications in a research program. We have to be aware there could be benefits, there could be side effects. And one difference in a research program is the people are often followed much more closely.

Jimmy Choi: And it's important to know your risks. And I think that's a great point, Stuart, is that even when changing your medication in terms of your treatment protocol, you have to understand. I think for me, I ask a lot of the same questions when it comes to clinical trial participation that involves therapeutics.

So Kevin, the clinical participation can take a lot of time and travel because we've already heard Paulina and Stuart mentioned that some of these trials are held all over the country and some people are asked to travel in. What do you think about that?

Kevin Kwok: Yeah, I've been involved in trials where I've flown back halfway across the country just to participate. In many ways, I feel more attached to the medical team that's there when I do that. It's a commitment and sometimes ... I was involved in a DBS trial and the DBS company flew down engineers and we all convened and to me it was a real collegial experience. So that's one of the things that I think is very positive.

I will make a caution that there are some trials that people travel to which are not bonafide trials and those are sort of these, you see them, it's like they say, "Oh, join a trial, you pay $5,000 and you'll get a stem cell therapy." That is not a bonafide clinical trial and you have to be very careful about those type of things.

But focusing on the positive sides of clinical trials, if you participated in a clinical trial and you've seen an approval, I can't tell you the joy that I personally felt of contributing to the medical body of knowledge by being involved in a trial that has now come to market. To me, that's one of the real joys of being in the role of a study participant.

Jimmy Choi: I'm with you on that, Kevin, because I've also, in terms of positives, things that I've personally experienced, as I mentioned, I was involved in the early on forced exercise study and I made a lot of lifestyle changes based on that study. And today as we're getting more and more information and more and more data coming out from other trials that are being run in terms of intensity exercise, it reaffirms that what I was doing before was making an impact and it reaffirmed that the changes that I made in my life were in fact, at least based on the data, were good changes. So I think that's one of the biggest positives that I personally received.

Now I wanted to bring the conversation back to Paulina here. Paulina, I wanted to ask you, how might participation in a clinical trial today affect eligibility for future treatments and/or trials?

Dr. Paulina Gonzalez Latapi: Yeah, I mean, I think that's a common question that people might have and maybe one of the things that might deter some of my patients from participating in trials. I get that question a lot. So it's a difficult question to answer because it might depend on the type of trial. But I'd say in general, based on the trials that we have right now, it should not change the type of treatment that one would be eligible for or participating in a new trial.

In most cases, when someone is participating in an interventional trial, you would not be allowed to be in several trials at the same time, but a lot of the times these trials allow for participation in a new trial after a period of time has come by.

I mean, one consideration could be some trials looking at advanced therapies like deep brain stimulation for example. So that could be a limitation for certain trials. So again, we come back to that eligibility criteria, just making sure that what we're testing is safe for the person. But I'd say really in most trials, this would not be a limitation and that's also where it's important to have a good conversation with the study team and with your own clinical team to make sure that you're the correct person for the trial.

Jimmy Choi: Kevin, I'm going to make this a little bit personal for you and I. Personally, I'll be the first to admit I'm guilty of this. When I first started participating in clinical trials, I didn't ask my wife. I just went and I did it. And now I know moving forward, I would never do that again just because it's not just us with Parkinson's, our families lived with it. So when it comes to care partners, I wanted to hear from you what your thoughts are about the care partner's role when it comes to clinical trials and also if there are any specific questions that they should ask.

Kevin Kwok: Well, first of all, Jimmy, I'm just like you. I did the same thing. I sort of did it on my own in my own renegade way, but my feeling today is that you should include your partner throughout. My care partner now travels with me to all the trial sessions with me and she observes and she also gives input that things that I might not see or know about. There's a certain machismo that we have where we may overlook things or we may just say everything's great and your care partner gives you a more bonafide, legitimate view of what you're really like. So I now look at trials to look at, do they provide travel for your care partner? Do they serve a meal for them if it's an all day trial? Little things that really might make a difference because we can't go to some of these day by day without a care partner supporting us.

Jimmy Choi: Kevin, I know you already talked about what types of things that people should consider or what type of questions that you would consider, but now I guess if someone came to you for advice and they said, "Hey, Kevin, what do you think are the things that I should consider before joining a clinical trial?" How would you advise them?

Kevin Kwok: Well, I'd first ask what is it that they hope to get out of the trial, and then I would start to ask a little bit more question about the way the trial protocol has been designed. If it's a safety study, I'm a little more cautious about just diving in without finding out a little bit more about what other safety information can you provide. Now, if you're going into a registrational trial, it's more of the question that you ask afterwards, will I be able to have access if the drug is safe and is efficacious? So it's really starting to drill down into details of the study specifically for what you're able to participate in. I guess there's so many levels that you can get down into once you really start looking at an individual trial.

Jimmy Choi: I'm with you all the way on that. That's good advice. Paulina, we've been talking about clinical trials and participations and questions. Can you walk us through the typical steps of participation?

Dr. Paulina Gonzalez Latapi: Sure. So I think, well, participation starts when either someone finds a trial in the Fox Trial Finder and reaches out to the study team, or if they're seen by their physician and if I see someone who could be eligible for a clinical trial, then I refer them to the study team. And then again, we want to make sure that we are offering this opportunity to the people who are going to be safe and who are going to help answer the question.

So some studies might have a pre-screening stage where the study team might reach out to them and just confirm the age or the diagnosis or the medications they're on. This pre-screening phase would be more about answering the question, is this a good fit for the person? And then if it is, then most studies will start with a screening visit. So that's where we ask the participant to come into the study site and then we'll do a more thorough assessment and exam, ask a little bit more questions just to make sure that the person fits all the criteria that we want to be able to answer the study question and to be able to make sure that the person will be safe in our study.

And then before someone even decides to come into the site, we also provide what's called the informed consent. So this is about making sure that if someone is interested in participating, if they're a good fit for the study, then making sure that they understand very well why are we doing the study? What are the possible side effects? What is the time commitment? Who is the contact in our research team if there should be any questions? So making sure that whenever someone decides to travel and to come in for that screening visit, that they have all the information that they need.

And then during the study visits themselves, it will depend on the trial, but for most studies it will be a combination of answering specific questions about symptoms, an exam that might look very similar to the exam that the neurologist does in the clinic. Most trials will involve getting some sort of blood sample. Some studies will also involve some imaging or even a lumbar puncture, so it depends on the trial.

And then again, I think we're moving more towards being able to give certain results, especially for observational trials, so those trials where we're trying to understand the disease better, trying to be able to give participants some of the

results for the assessments that we do during the study visits. When it comes to interventional trials, those results might take a little bit longer because again, it's important in order to ascertain whether a medication truly has efficacy or not, we may need to wait until the study ends before we are able to share some of these results with a participant.

But that's also an important part of the study. It's just again, we acknowledge people are taking the time to participate are helping us move forward in our knowledge about Parkinson's disease. And so more and more, it's very important as a study and research staff to also make sure that we are giving something back to the participants.

Jimmy Choi: Kevin?

Kevin Kwok: It's really important for patients to know that you have the opportunity to opt out anytime if you're in a clinical trial and the informed consent should state that.

Jimmy Choi: It's a very good point. So thank you for bringing that up. I was just going to mention that one of the most important thing that makes clinical trials successful is communication between yourself and the team and your own care team.

Stuart, if you wouldn't mind, what should participants know about communication with the study team and whether or not a study team communicates back to their patient's care team?

Dr. Stuart Isaacson: Well, I think it's really a team. And I think when you join a study, you're joining a team, a team of investigators and coordinators at the site in communication with your primary care doctors, internists, neurologists, movement neurologists, and also a team that goes above into the pharmaceutical company to people who monitor the safety of these programs and ultimately to the FDA as well. And it's all a team approach of trying to get an answer to a question and being part of that team.

So when you begin a research program and you look at the informed consent document, you'll see that it says that unless you object, your doctors will be notified. You can bring a letter to them or a letter can be sent to them. You should carry one with you, so if you wind up an emergency room or a new doctor, you can show them what you're part of because they can't look it up in a book. It's something new. It's on the letter. They can go to a website and look it up or call the study team to get more information.

And throughout the entire process, you want to be able to stay in communication. Of course, you may not know if you're randomized to get active drug or placebo drug, but we're still able to give that communication and get on the telephone. And most of our study participants, maybe two-thirds come from our clinics, but about one-third come from all over the country and travel. So we have to stay in communication with whoever they're seeing around the country.

Jimmy Choi: Now, I just want to talk really quickly about what happens after a study ends. And Stuart, if you can maybe just provide us with some information about what generally happens after a study ends and what people should expect.

Dr. Stuart Isaacson: Yeah. So if you join a trial and you participate in the study, it may end after three months or six months or a year or two. Or if you're an open label extension, it may continue until the drug is either approved by the FDA and it can be marketed or finds out it doesn't work for most people and that study may end.

But when the entire program's over, good clinical practice would dictate you will be informed of which arm you were in. Of course, this is going to be much later than when you were part of that trial. And if you have any issues that occur at the trial, you still want to let your study team knows, but hopefully the trial winds up showing merit and the drug being approved and being available to everyone and you were able to get access to it five or eight years earlier.

Jimmy Choi: Great. Thank you. So the first question is, let's see, is a clinical trial a way to get access to medication that is not yet available? And I'm going to open that up to Stuart or Paulina. What are your thoughts?

Dr. Stuart Isaacson: Yes, this is a way of getting access to tomorrow's treatments today. Truly, for an example, many are aware of a lot of the advocacy and awareness campaigns about hallucinations, then delusions in Parkinson's disease and a medication that's available, the only medication approved for treating that in Parkinson's disease. This medication was approved 10 years ago in 2016 and our first patients began using it in 2008. So they had an eight-year head start if they had that problem to have a new treatment to try. And it's similar for many of the medications that are currently available at the pharmacy level now.

Jimmy Choi: Paulina?

Dr. Paulina Gonzalez Latapi: I agree. I mean, I think that's the point of these trials. We're testing newer medications with the intention of finding medications that will slow down disease progression or medications that treat specific symptoms. Again, one has to go in knowing that there is a possibility that some of these medications will not show to be efficacious, but if they are and they are approved, then yes, the participants will be one of the first people to receive these medications.

Dr. Stuart Isaacson: Yeah. I think it's important also to think about, what's in it for me? You might get access to a medicine earlier. It might help a symptom that we don't have good treatments for right now. You might slow down the disease. And what's in it for the field? Well, everybody wants to do better for Parkinson's in general. We want better treatments in five or 10 years than we have now. And also what's in it for you is not just what might happen medically, but you're part of something, of being involved, of understanding where medicines come from. It may be fun to be part of the coordinators who often are engaged and can teach you about things and you teach us about things. So I think it really goes to that idea of a partnership.

Jimmy Choi: Another question is that studies often happen at centers that could be far away from people. The question from the audience member is, why don't they take place in more areas than specific sites?

Dr. Paulina Gonzalez Latapi: So I mean, I think this is something that we acknowledge as well as investigators. And there's a couple of factors to take into account. For some trials you need to have the movement disorder specialist that's examining the patient, you need to have the facilities in place that will, if we are taking blood samples, for example, that we'll use to process those blood samples in the correct way so that we can, again, get the answers that we need. Some studies we might need specialized kind of imaging that's not widely available.

Now having said that, I think we are also trying to be more creative with the way that we design our trials and more and more we're seeing some trials trying to incorporate some remote assessments. So using technology that's available nowadays such as certain smartwatches or certain apps for phones so that we can try to extend the areas where some of these trials are being held. So I think hopefully in the future we'll see some of these changes, but the reason that these trials take place in such specialized places, it also has to do with the information that we're collecting right now.

Jimmy Choi: Yeah, standardized, right? Standardized collection of information.

Kevin Kwok: One of the writers said that there needs to be more diversity in trials, for instance, having more women in trial. I cannot emphasize that enough that we try to create a broader base of volunteers of different backgrounds because that really is how we get to that answer.

Jimmy Choi: I want to thank you for bringing that up, Kevin. I think there's so many things to consider. Women have such a different experience than men, but on top of that, also we're talking about other minority groups as well; African-American, Hispanic-American, Asian-American, these are often underrepresented in clinical trials. So for those of you in the audience who are watching and you happen to be in these minority groups, I definitely would strongly consider you at least consider looking into participation in clinical trials.

I'm going to ask one more question, and we touched on this briefly in the webinar itself, but Stuart, I wanted to just bring this up because this is about future eligibility. I mentioned that I started and participated in clinical trials earlier on and not so much today from the participant side, but really more from a research end today. And the reason for that is because I've been diagnosed with Parkinson's now for such a long time that there are fewer trials that I qualify for.

So the question that came up in the audience is, it's really concerning about future eligibility. I wonder if you have any additional thoughts to add to that?

Dr. Stuart Isaacson: Yeah, well, it's hard to really predict the future. We don't have that crystal ball we all wish we could look into, but there's almost always a trial that one could qualify for. And we have so many trials going on for all different types of stages.

There are studies that just look at a wearable to studies that look at genes, there are studies that look at imaging, studies that test medications. So there's often going to be something if you're medically healthy and it's safe to do so. So it's just a matter of looking around and seeing if it's something that's right for you and be aware that even when you sign informed consent and you do a screening visit, you still have three to six weeks in most trials to change your mind before you ever get the medication. So sometimes it's worth dipping your toe in the pool and seeing how it is and then deciding to continue or not.

Jimmy Choi: Hey, Kevin, in the last minute left that we have left here, people are probably wondering how do you handle disappointing results? What are your thoughts on disappointing results?

Kevin Kwok: Well, there's a saying out there when you're in the pharmaceutical world, there are no failed trials, but there are trials that we learn something new. And so I think it's really important not to feel that you've been involved in a trial with negative results. It's just that what they were trying to prove didn't play out. Sometimes that's based on dose, sometimes it's based on the right patient or the right stage of the disease. There could be many different reasons and it doesn't necessarily mean that you have abandoned that trial or that product. There's still things that can be learned.

Jimmy Choi: Yeah. So what I'm hearing from you, Kevin, is that even in failure we can learn and we've eliminated something that doesn't work. We can focus on something else that may work and that brings us hope.

So we're out of time, guys. I know we can go on for a long time, but I want to thank everybody once again for joining us today. And of course, thank you to our panelists for sharing your time and your expertise. We hope that you have found today's discussion helpful and I hope that you guys all have a wonderful day. Thanks again.

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