Understanding Clinical Trials And The Role Of Foundations In Parkinson's Research Transcript

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Introduction and Guest Welcome

Welcome to the. Parkinson's Solutions Summit 2.0 I'm your host, Dr. Ken Sharlin. And today I have a special guest. Someone I've known for many. Years.

this is Shawna Tindall. She is the clinical research director here at. Sharlin Health Neuroscience Research Center, and she has been working with me pretty much since our.

Doors. Opened back in about 20, late 2015 to the Parkinson's Foundation. And we'll probably segue a little. Bit into talking about the importance of foundations as well, and supporting.

Research as well as services to people affected by. Parkinson's, since as well. As. Providing grants, etc.. To the researchers who. Are involved in developing treatments in the first.

Place. So without further ado. Shawna Tindall, welcome to the Parkinson's Summit Thank you, thank you, thank you. It's a pleasure to be here. Well, as you know, research.

In general, neuroscience. Research has really skyrocketed. we started. Doing. Research together. On an MS Study back. In 2016. Correct. And originally it was.

The we. Had one study. It was a it is a drug called ofatumumab But and. As a result of the studies that were all related to. That one compound ofatumumab was eventually.

FDA approved. And is now called key symptom and is really one of the most. Efficacious. Treatments out. There for multiple sclerosis. So with that trajectory, our research center has really exploded.

in a couple. Of years later, a few years ago, rather, as you know, we, Launched in Alzheimer's. Disease trial. And that was really sort of the pivot point for our growth as a center.

Yeah. We, try to we have. An interview. As part of this summit with Dr. Peter LeWitt. that was. Done by. Dr. Barbara Pickut, my. Co-Host. For this summit.

And Dr. LeWitt, is. Talking about what's in the pipeline for Parkinson's research. But what I'd really like to do, because we do get a lot of questions.

I'm sure you may even get more questions than I. Do, is talk about research more broadly, like, for example, we have a. Patient whose husband reached out to me.

about a well. The patient happens to have multiple. Sclerosis, but this is very applicable. And he got on, you know, the. Computer doctor Google, as I call him.

And, he found out that there was or is a what's called a phase two trial. We talked about what that is called. And investor gains compound. So it's not.

Approved. As you know, there are many, many arms trials.

How Clinical Trials Are Started and Run

There are many, many Parkinson's trials. But he was very intrigued by this trial. And he emailed me and he. Said,

what are. Your thoughts on this treatment on this drug?

And hoping that. He could get that. Treatment. For his wife. And I explained to him. That. In in general. During the. Development. Phase of a research based compound, a drug that is.

Not. FDA approved, it is. Actually not. Possible to reach out. To the pharmaceutical company. Or the. Organizations that that. Sort of navigate studies.

For individuals. That cross. and. Say. Hey, can I get this investigational drug? I heard that, you know, a lot of people, they're very intrigued. I get a lot. Of emails.

About, hey, have you heard about this? Have you heard that this is a possible do this? But clinical trials are very regulated, very controlled because we've been through a little bit of what as a research.

Director, when we're. Approached about a. Clinical trial and we. Get, well, how many would. You say on a monthly. Basis? We're we're we're approached about a, oh.

Probably probably 7 or 8 at least easily some some month, probably more than that. Takes a lot of work. And it's there's different stages. And this. Is just about.

How an individual. Site like. Sharlin Health Neuroscience Research Center may. Be able to acquire or participate. In a given study. Many of these, of course, have multiple.

Sites around the country and multiple sites around the world. Because the goal may. Be to enroll, you know, 500 and 800,000 people in a. Given trial. So each individual site.

They might have. One, they might have. Ten, 15 subjects. Hands on the trial depends on how common the condition is. You know, obviously it's probably a little easier to.

Recruit in general. but it's really a huge process. Even just from the moment. That we get we're contacted, right? And they say, oh, we. Represent this pharmaceutical company and.

we would like to gauge. Your interest in possibly being a, a. Site for our, our trial. Can you, can you kind of. Just really the basics. Is I want people to understand. That this is really.

We're very honored to participate in these trials and to. Have brought, you know. Between a key symptom and more recently, donanemab for Alzheimer's disease to market.

but it's it's a huge undertaking. It it really is. So it starts basically because the pharmaceutical company is reaching out to gauge our interest. So we're each sort of trying each other on our side.

They want to make sure that we're going to be able to provide data that's helpful to them to bring their drug to market. So the relationship has to work for the site and the sponsor.

So which the pharmaceutical company, once they, once they select, you have to fill out questionnaires. And then once they decide that, we're suitable for them and then we decide that, yes, we like the trial design, we think that we can bring some patients to that.

We think that we can have things that are good contributions for that trial. Then we go through we have to do all the startup elements. And I think that sometimes that's where a breakdown happens with people that are interested in participating in clinical trials, because when we say, oh, hey, we're going to be starting this trial soon, they I think they just don't realize how much is involved in starting those that it's not like they say you get awarded the trial and then boom, you're ready to start enrolling patients.

You have to get all the right equipment and you have to train the staff, and you have to do all the things to to put

everything into into place to actually execute the trial because you want it.

Is an investigator product. Whenever you're dealing with drugs that haven't been approved to by the FDA. So patient safety is always, always the the first priority, both with our site and with the pharmaceutical company.

So we have to make sure all those measures are in place. And then once we have everything into place, then we can start going through the screening process of making sure that a candidate is not only right for the trial, but the trial is right for the candidate.

So I think that that's one of the things that makes us very successful is because we work very hard as a team and you as a physician, to ensure that this is the best fit for the for the patient as well.

We don't just put patients in trials to fill numbers. We do what's going to be best for both for the both the patient and and the, the pharmaceutical company.

So I mean, there's quite a process involved. And that. That's really important. And it sort of alludes to two really important points. One is. That all of the.

Individuals on my on the professional side. You, your team, research coordinators, myself, all. Of the other. Investigators, raters. And things like that.

We all have to go through a. Certification that. It seems like you have to do it over and over again because, you know, I did it for. This one, but, you know, then you.

Have another company say, well, you have to do ours. And that's called. Good clinical practice. It's so. Important that people understand. That, the everyone involved, the federal.

Government, independent. Review boards, You know, the pharmaceutical companies themselves, a. Clinical, Research organizations are very committed to something called.

GCP and all its related. Certifications, meaning. That the clinical trial. Design must be. Considered ethical. Right? Right. That that that's why there are there are measures in place at the pharmaceutical company with the independent review board, as you say, that's an ethics committee that's independent of both the site and the pharmaceutical company that putting on the clinical trial and then the site should have those measures in place to make sure that everything is done ethically as well.

And then in addition to that, when. Individuals are identified and they go through. A screening process, part of that screening process is something. Called.

An informed consent. So if you receive. If I'm a subject, if I'm potentially I'm thinking about being part of a given trial. how do you how do you. Explain to me, if you don't mind.

broadly. Again, not for one or another. Specific trial, but what. Does it mean to consent to subject? And what does. That look. Like when you're sitting down with them?

Because it's so important, of course, that they understand what they're agreeing to. Absolutely. So what we try to do, you as, as our physician, do a fantastic job of free input or really giving patients information like broad information about a trial.

And then we go in and we like to explain it a little more in detail. And I try, if possible, the whole team tries to make sure that we send that consent that is provided to us by the the pharmaceutical company, to the patients that are thinking about being in the trial ahead of time.

So that way they can read it over as slowly or as quickly as they want to. They can write down their questions. And we do have patients that come in with notebooks of questions.

And what we do is we go into a private room and we go over a page at a time and make sure that we're answering questions and that the patient fully understands as where as well as their family, who often acts as caregivers and in certain therapeutic areas, we make sure that everybody understands what the commitment is that that they will have to make to the trial and what the pharmaceutical company is committing to them.

You know, one of the key things that we want to make sure that they know is you can stop at any time. It doesn't matter. You don't have to have a reason.

You can just come to us and you can say, I don't want to do this anymore. But by the same token, we always tell them that you, as our physician, will also have that same right to say, hey, you know what?

I don't think this trial is working out for you. So I think we need to go a different way for your care. So that's one of the big things that we make sure that they understand and their concerns.

Often they break it down into really, really easy, bite sized pieces to understand. Because when you look at a at a trial design, it's very overwhelming.

It's very technical. It's all kinds of medical terminology. And and it wouldn't be a protocol if I didn't have to look up words. Sometimes just being honest and and saying it.

So what the team and I do is we will read the informed consent first, because then that allows us to understand how we can explain the trial, because that's the point of view from the pharmaceutical company.

It explains what they can expect in the trial. It explains what's going to happen at every single visit. It explains monetary compensation, which is often the case in clinical trials.

And it also makes sure that it explains, hey, if you don't think that we're doing a good job conducting this trial, or if you don't think this trial is set up, well, this is who you contact.

It gives you the information in writing on who you can contact as far as safety and efficacy. So those are the key things we highlight. Absolutely. And I definitely want to talk about that compensation piece.

Because as you know, we've. Encountered situations where. quite honestly. There are. Clinics. Or medical facilities. some of them are in the United States, some of them are not in the United States, and maybe in the Caribbean or Central or South.

America, Attracting people. Telling. Them that they're doing research. But they're. Actually making them or asking them. To pay to be part of this research trial.

Right. And and. While that may. May. Be legitimate. More often than not. It probably. Is not. Right. Not there are exceptions. Read it written into regulatory.

you know, language by the FDA. But by and large, subjects do not pay to be in a clinical trial. Correct. So they we kind of touched on it briefly whenever we were talking about phasing of the trials.

Just a just a quick, easy rundown on there are four phases of trials. The phase one is they're just evaluating a very small group of people to make sure that the drug is even safe.

And often those those people are healthy people. They aren't even the people that the drug is intended for. They just want to make sure that it that it's safe.

The phase two, it includes a broader group of people, not that much broader, but it's dialing down the dosing. And now we're looking at patients that actually have the indication for what the drug therapy is for phase three.

That's usually a larger group of people, which is oftentimes more thousand, like what you were talking about earlier.

and these are generally the steps where we've dialed in the dosing, and now we just need more data to take to the FDA.

So it's one step before approval. Then you have phase four, which is generally what's conducted after a drug has been approved by the FDA. And it's that that point that you could be in, you could participate in a trial that they call a real world trial.

And I use that real world trial because it's a trial that is commercially available. Typically it's a drug that the commercially available at that time.

So there in you might get into your expense where your insurance might, they might want you to instead of getting the investigational drug for free like you would before it's approved with the FDA, you would run it through your insurance, just like you would do, in a outside and at your doctor's office.

Ethics, Consent, and Trial Phases

Right. So that would be the only term that you wouldn't actually be paying, like Charlene Health Neuroscience Research Center and people wouldn't be paying us to participate.

They just might have to buy their drug or run labs through insurance or something like that. Yeah, by and large. We I think we. Found that. The later stage open label, what we call phase four post-marketing studies.

Even in those situations, in my experience, for the most part. part of the broad. Renumeration, if you. Will. Not just financial, but. A your. Willingness to be in this. Trial.

is sort of compensated by the fact that we're going to provide the, the treatment, if MRI's, Pet scans, blood tests, anything, all of that is covered by what we refer to as the sponsor.

correct. Which is generally the pharmaceutical companies. So, the nice thing about those. Trials. And we'll probably want to talk. A little bit about placebo.

But in the. Phase four or. Post-Marketing post. Approval studies, the. Sponsors are getting long term. Data because a lot of trials, you know, if. You're a pharmaceutical company, I know these are.

Very wealthy. Companies. Many of them, not all of them, some of the very small companies. That we deal with. But if you're talking about Eli Lilly, Pfizer, AbbVie, etc., they yes, they.

Have trillions of dollars and all that. But it's still very, very, very. Expensive. To bring a drug. From the. Lab rotary all the way through phase three and all the regulatory.

Expenses. Associated with it. Ultimately, to make it a commercially. Available product. So there are, of course, guidelines. There's FDA oversight. But in.

General, the goal is to get it through as quickly as possible because. You know, time is money. And. Right, if you dragged a study out for five or. Ten years. Unnecessarily without.

Bringing it to. Market, then that's a very expensive proposition. So, yeah, there are statistical, tools that are used to determine, you know, what size, population.

How big should that study be? How many people need to be enrolled? How long does that study have to go. On for in. Order to to detect a statistical. And clinical, clinically meaningful.

Signal that the. Treatment is effective and worthwhile. And at that point, that goes in a study design. And that's generally your phase three trial. But those phase four trials, you know, they could be five years long, right?

And they may even be mandated in some cases. By the FDA, like we're going to approve this drug, but we. Want you to continue to collect. Data. Right? Yeah, definitely.

And that's where I think that I think that's a good segue into talking about placebo, because a lot of times what you're talking about is, hey, yeah, this drug works, but does it work better?

Does it work better than the drugs that are already approved? Is there is there a need for this drug out on the market? Because if you take, if you take a therapeutic area like multiple sclerosis, there's like, what, 27, 27 FDA approved drug treatment therapies.

And so now at this point, it becomes not not unethical, but it becomes just not something that they, they would want to do for long periods, the time to try to compare their drug that they're trying that's investigational against a placebo, which is a, what's the best way to describe placebo?

well, it's a non-active where in there you go. Pound. It could be a I. V. bag that looks that, you know, may look like. Just normal saline doesn't. You know, you.

Can't. Necessarily see the. Drug in the fluid. You know, it might be, An unmarked. Tablet. and there are various. Ways in which that's used. In some. Trials, it's still possible to do placebo.

Controlled. Trials, but for shorter. Periods of time. In other trials, it is. Actually considered. Unethical. in some. Cases, because if we're studying epilepsy, for example, there really aren't is.

To my. Knowledge, placebo controlled trials in epilepsy. Anymore because. By and large, the people that are volunteering for these trials, they have. Poorly controlled. Seizures.

They have. Been through many of the conventional treatments and their various. Motivators, reasons. Why. People choose. To be in a. Trial. but if they have brittle, you know, epilepsy, where they're having lots of seizures.

You would never put someone on. you know, risk. Putting someone on. Placebo because they they could die. Right? Right, right. This is a really disabling.

Can be a. Very disabling disease. The good news. Today is that the. Treatments are. So efficacious that, you know, you you can. Get on a key symptom and not.

Have a relapse for. 20. Years. but. Right when there are very few treatments available, for example. In Parkinson's. Disease, while. There are many. Approved drugs for. Parkinson's.

All of the approved drugs for. Parkinson's are approved under. What we would. Call symptomatic management. You're right. Removing the symptoms. You're improving motor control. You're improving.

Whether. It's, you know. Just something as basic as leave a Dopa cavi Dopa or recently approved, Correct sign, which. Is, essentially still leave it open carby dopa.

But it's. Neil's flagship product. was just approved a few really. About a month. Ago or so. Right. but the. Bottom line is it. Only improves. Symptoms.

It does not. Slow disease progression. Over time. So in a Parkinson's study. It's very likely at this point that if you're studying a. Candidate compound.

That's perhaps thought to be. Disease modifying, like something that. Helps clear the alpha synuclein, right, targets. Alpha synuclein, the protein. That we talk about a lot.

That accumulates in the brain, the skin, the gut and Parkinson's. These are probably. Going to be. Placebo controlled trials. that that's typically what we see in ind indications that don't have a lot of available therapies out

there.

And that's the best way to get to them. Whereas when you were talking about it being less likely for people to be on, on a placebo because of, of ethics such as some one on epilepsy, what we see in trial design at that point is they're allowed there when you're doing a clinical trial, you have a list of what they call prohibit prohibited medications because they just they don't want to include factors that will muddy up their data.

They need to have good clear cut data to take to the FDA to say, look, this is why our product is going to help people so that they can show them that nice, clean data and whenever they lead them on other drug therapies, sometimes that can muddy up the data.

So whenever they're doing trial design, they have to keep that in mind on these indications where it would be unethical to take them off of drug, because if I'm somebody that has epilepsy and you tell me, no, you got to stop this drug that sort of work in on your seizures to try this drug that we don't know what it's going to do for you.

I'm not going to be super excited about jumping on board with that. I feel like. So, so a lot. Of times these. Are this. Is why in the area of. Epilepsy, the. Treatments that are being investigated.

First of all, there's no placebo controlled trial. And secondly. the. Compounds that are being investigated as potentially. Effective drugs are they're referred to as.

Add on or adjunctive. Therapy. Right. and eventually some of them do. Get approved later. On as being. Like, if I had newly diagnosed with seizures, I could start this drug and it would be the.

Only thing that I would be on. But by and large. It's very hard to do those trials. Anymore. Because you would have to be. Approaching the trial with a completely clean slate, meaning.

Right. Treatment resistant. Epilepsy. And you can put me on a drug and there's going to. Be a placebo group. Like I said, that would be. Potentially quite dangerous and even life threatening.

So we have to leave. People on their meds. Those meds have. To be stable for a. Certain. Period. Of time. And that. That what is what. Defines that. Of course, is. The.

Individual trial protocol. It's written into the. Protocol. And will vary from. Trial to trial. And this really important folks, because if you're thinking of being in a Parkinson's trial, let's say you're in discussion maybe with an independent research.

what? center like ours or a research center that maybe is affiliated with. A medical clinic. Overall? maybe you also have a primary care doctor. And I know that, you know, everyone cares.

A lot about you. So, for example, Again, this would come up saying in Alzheimer's. Trial, there's a very old. Medicine's been around for. Probably 30 years called donepezil or aricept.

It is only for symptomatic improvement, memory. It does. Not slow disease. Progression. And let's say. You think about a trial, you've already. Had some initial contact with the research centers.

They you know, we're very interested in having you. If you're. Interested in this. Trial. And then you go to your primary care doctor and they go. Hey, has your neurologist started you on this drug yet?

And, like. No. Well, you. Should be on this medicine, right? So that's a huge mistake, because what will happen. Is. If they. Put you on. This drug, I'm making a specific example, which is.

donepezil or aricept. And then you come back. To the trial, though. Oh, by the way, my primary. Care doctor a couple of weeks ago. Started me on did that. Bazil.

Guess what. Can get kicked. Down the road? You have to be. Stable on that drug. For a. Certain number of potentially months. Months. So now you. Can't be in that. Trial.

So once that. Ball is. Rolling, even if you're not yet in the. Trial, it's really, really. Important to keep things kind of on an even keel and to. Check with the.

Trial center. If you're considering a treatment, to make. Sure if you're really. Motivated to be in that trial, to make. Sure that. There's no contraindication where it doesn't, you know.

Delay trial participation. Because even if you even if you bring it up to your physician, whether it's a primary care physician or a specialist or whomever, or even if you say, hey, I'm thinking about being in this trial, it might not be something that they think about, that that might be an issue.

So, I mean, don't rely on your physician to know the ins and outs. It's something that you're going to have to make sure that you're actually actively talking to the correct people about.

It's right. I actually had that come up very recently. It was even more subtle than that. Patient was already on that drug. Didn't that. Bazil, which. Has some different.

Dose levels? five milligrams. Dose, ten milligram. Very rarely. Use 23mg. But anyway, they were already on it. They were. Stable on their. Med. This was a follow up visit.

We had started a discussion about clinical trial participation. Said, oh, by the way. I saw my primary. A few weeks ago. He thought I should go. Up on my dose of didn't happen. So.

Nope. Yeah. Can't do. That. Right? So if you. Really want to be in that. Trial. You cannot even go up on the. Dose because that would be considered a change.

So but that. Brings in a whole. Other level. And we were talking about placebo. And we really want to emphasize that. Technically speaking, when we're all certainly hopeful, especially by.

The time a investigational. Drug gets to what we call phase three. So they've already been through, you know, some. Dose at dose exploration. You know, what's going to be the. Best dose.

They've already started to look at. You know, things. Like, you know, early signal as. To whether or not there could be any. Serious, side effects. Adverse events.

Associated with the medication or. Treatment. And by the way, that, you know, starting a the big phase three trial, the pre FDA approval trial.

Placebo, Blinding, and Trial Design

Does not mean that we know everything about. These. Treatments, right, in terms of. Their safety. So, you know, we'll know. What we know because they've been through this phase one, phase. Two.

But, they're still collecting safety. And to. Be clear, we're also. Collecting data on ultimately on. Efficacy. So while it's very attractive potentially, especially.

If you're diagnosed with. Parkinson's, you're like, well. This wasn't in my life plan, you know, and I have my retirement. That I've, I've saved. And we have. All kind of you have. Travel, you know, we.

Have grandchildren. All the things that people. Look forward to. I want to. Play golf, whatever. and then, you know, I'm hit with this diagnosis and it's.

Really. Thrown me. For a loop. And there's no. Approved drug that is disease modifying therapy. We talked a lot. In

the summit about things that are lifestyle medicine or environmental, medicine, regenerative medicine based that may have an impact in in terms of.

Drug approval. No disease modifying therapy. And then. Folks go, well, I really. Want to be on the on the study. Drug. Right. I really want to be on the study drug.

I don't want to be on placebo. so that brings a whole other element, to the discussion about. Blinding, randomization and. The. Realization that. This is a trial because we.

Don't. Know if. The treatment's actually more effective than placebo. Right. So in those a lot of those instances, like you brought, you brought up, donanemab with Eli Lilly a lot of the trials, it might be that you're on one or the other, whether it's active trial drug or you're on placebo for a certain amount a month and maybe half of the trial, and then the last half, you're on the opposite to give everybody a chance of being on placebo.

But I mean, on active drug. But a lot of things we get is, well, I, I want to be on active drug. I don't want to be on placebo. We have to tell them, you know, this is the way the trial works.

If you're patient, you know, you get to be on drug if you don't start out on drug. But a lot of the trials are also designed in so far as that. If your disability progression gets worse, they allow you to become on what's called open label, which means we know you're not getting placebo.

We know you're getting the investigational drug at that point. Or they have. When you talk about blinding and unwinding, blinding just means that, there are certain members of the team that don't know if you're on investigational drug or you're on placebo, and often you as the physician, you don't get to know that, because then that would bias how you treat that patient accordingly, which in turn would muddy up those data that that we're trying to give the pharmaceutical company.

So because if you were to say no, that that patient X was on active drug and patient Y was on placebo, then you might be inclined to treat patient X differently.

If they say they both came down with chest pain. You know, you might be inclined to react differently to patient X that is on drug as you would on patient Y.

That's not on drugs. Because with patient X you would say, oh well I mean he's on any drug that could be it. And I'm patient y you it well he's not on study drugs so we need to send them to cardiology.

It might change the urgency and how you would treat a patient. So they make sure that they keep those findings in place. That's very, very important to get that clean data.

Unbiased data unbiased. There's something called. A placebo effect. And also we use the term sometimes nocebo effect. If you believe that. Something is going.

To help you, it actually may more than likely help you if you believe. Something is going to hurt you in some way. Cause side effects, it more. Often than not causes side effects. And I've. Heard.

Discussions industry discussions. Where. The primary or principal investigator. Or like myself before the trial even starts, let's say you're. A potential. Subject. Seana.

And I say Seana. we have this really. Fantastic clinical trial going on. I'm super. Optimistic about the. Potential for this treatment. To help people.

And I. Really think you would. Be an excellent candidate. Well just. My saying. That to you if you go into the trial. Can introduce. Bias. Into. The trial.

And. Affect how you respond to the. Treatment. That is true. But I mean, mindset, and I'm sure as you've talked

throughout this summit about lifestyle, I mean, when you treat mind, body, spirit, that's the mind part, right?

I mean, because you you have to think in your mind that it is going to work, which changes your positivity, it changes, it changes your outcome. And there is actual data that says that that's the case.

And like you're talking about the placebo effect, I think it's something like 43% or something like that, isn't it? In some trials at this point. In trials, it's very it's. Become it's. Highly.

Problematic. For. Companies developing treatments in my brain. Because the placebo effect. Has gotten so strong in my brain that it that in the end, you know, the.

Goal is to show that the active drug or investigational drug is superior to placebo. But if you have a really high placebo response, it gets harder and harder to show that the drug is effective.

Right? Right. So definitely, I mean, but by that same token, with you saying that whenever you are telling our patients that in speaking specifically in our practice, our patients put a lot of trust in you as their doctor and as the leader of the trial that they're participating in.

So I think that when your patient trusts you as a medical team, that that can lead to longer patient retention and better patient outcomes and just an overall really successful make up of a clinical research center for both the patients and the pharmaceutical companies that are trying to prove their information about their drug.

And yeah, it's a. It's a fine line to walk. Because. On one hand. You know, we. Do want to. Recruit. Patients to this are very important. Studies. You know.

To have, for the first. Time in modern history. To approved. Treatments for Alzheimer's. Just as an example. for anyone out there who's. Been connected to someone with Alzheimer's disease, I mean, and watched them, you know.

Deteriorate tragically over. Time and to now have two treatments, I mean, that. There aren't perfect. Treatments, but that certainly gives us hope. And so.

Obviously. We know much. Less about the. Potential for benefit. For an earlier phase trial, because it. Is an earlier. But when we. Talk about phase three trials, I do say, you know, the data.

From the phase. Two trial is very. Promising. Would you consider part of that? But I do also try to balance that out with. The understanding. That whether there's.

An active control. Or a placebo active. Meaning there's a. Comparator drug. We see this a lot in Ms.. Like I said, in. Epilepsy as well. That, you know, we don't.

Have any control of these randomization algorithms or computer. Generated, they, they. Have nothing to do with. Us. We can't sort of say, hey, it'd be really good for the placebo.

You'd be really good for the actor that that you that. Never, never, never happens. Right? Right, right. So, you know, we can only say, but honestly. So here's the study design.

And again, you'll have a full consent and, and people go into this understand that they may not. Start out. On the investigational. Drug. But to your point, there's very often some sort of.

Crossover or phase or a point during the trial where a. Certain end point has been reached, and at that point the trial participant. Is, is either, Openly offered an opportunity to be on active treatment or it may still be in the blinded phase, but they know.

That at. Some point in the design of. The trial, for those who started out on placebo, they will actually. Go on.

Active drug. they don't. Know when it.

Is they. Don't know. Right. or they may know broadly. They may know like. At the fifth visit. This is this. Happens. But since they know. What they started out on, if they started out right after drug, then they're on active drug to start a placebo.

They may be on active drug, but that's all. Blinded in the trial. As well. And one thing I'd like to note though, is that the sites are, unless it's a trial that the site itself initiated, which is called an investigator initiated trial.

And in that case, it's not an industry trial, which would be the pharmaceutical companies. It is not at the the site discretion to choose who's going to go into which trial.

That's decided by an anonymous database that just uses some particular algorithm that's set up by the industry sponsor, on that. And then whenever, whenever it gets to the site, that patient's the drug that that patient is.

Defense is not known to the site it's given which they're known by numbers usually. And the site doesn't usually know what it's dispensing at that point because however, their algorithm is set up through the through the trial design.

So it's not one of those things where, oh no, I'm really good friends with my doctor. I'm going to get on the active drug because I've got that backdoor set up so that that can't happen.

Exactly. And so the pills. Generally. Are pills or they're capsules or if they're if. It's something you're. You know, Getting. Say Ivy, it's very. Plain.

Jane sort. Of labeled a, you know, a white. Pill in an orange bottle. Or where. you know, the blister. Packs. And. Part of the responsibility of. Being in the.

Trial, not just the the, research. Team. That is, helping to execute the trial, but to be a trial. Participant is keeping track. Of your investigational. Medicine.

Particularly if it's. Something you're keeping at home. So there will be pill counts there. You have to bring your medicine in with you. You may be dispensed more than you actually need.

They may say, bring back. You know, you have to bring back, which hasn't been. Used. so there are a whole variety of ways in which, you know. investigational compounds are dispensed and.

Returned to the. Site. And then. There's levels of. Monitoring. So just. Stand that, you know, even though we. We are very good at what we do, we do a really our best.

We have a number. Of trial coordinators that are. Involved in all of this. Stuff. We still have. Monitors come in, and make sure that we're doing what we're supposed to be doing.

And they. They write a very detailed report. And sometimes we miss something. And hopefully most of the time we can provide. And it's kind of like the the bureaucrat that tries that has to, like, justify their job.

So they always find something. Right? Right, right. Yeah. That's not usually a problem. But yeah. So, part of your responsibility if you're a patient that's considering being in clinical trials and that's, that's the thing that that's covered in the informed consent is this is your responsibility and compliance.

See whether it's filling out a sub, what they call a subject diary and that what time you took what dose. And that way we could track it that way. And it's just a way to cross verify data, which is always what you're looking for.

Or you're looking for the FDA to approve these drugs. They want to make sure that all the eyes are dotted and that they're cross. So as a patient, I mean, it's your job to help do that with your participation by following all the rules

that are set at the beginning of the trial.

And if not, that can affect their data. Yeah. With Parkinson's. Studies, as with other studies, that could also include. Keeping an electronic journal that could.

Include. you know, because Parkinson's is a movement disorder. for example, there's a company, that, this time of the interview process for our summit, I believe they will be, part of this summit.

They're called Great Lakes. neuroscience. And they have developed tracking. Tools. To look at. Movement, abnormal movement, and people with Parkinson's.

So that, The treatments that are being investigated can be more. Objectively gauged as to whether that. Treatment is helping the person, let's. Say tremor. Right.

So you have this involuntary tremor and the drug. Is supposed to improve. The tremor. Well, it's not like you would. Just come in and say. Okay, well.

I'm I'm one of the, investigators. I'm going to sit down with you and do an exam and go. Mild, moderate, severe. You know, improve, not improve. That's very subjective.

It is. You have a tool, almost like an Apple Watch that you're wearing. All the time. It's measuring very in a very quantify way. You know, this. Sort of movement of my arm.

Then we can know again. Whether that, say, tremor has improved just based on what this tracking device has picked up. But it's the responsibility of the subject in the trial to take care of that piece of technology, to bring it.

In when they're paying it in for us to. Make sure that the data is. Transmitted. So it does ask a lot of folks. Sometimes it does. And a lot of times in those instances, those are presented as like a sub category of a trial.

So you might be on a trial where you're taking an investigational drug, whether it's a pill or what have you. Then you might have the opportunity that might be the main trial.

And then then this device that you might wear that might be presented as a sub trial, which means it would be optional. If you think that that's an extra responsibility that you might like, you want to participate in that trial.

You can participate in that sub trial, which would be wearing the device. So that in turn would be a device substudy.

Why Patients Join Trials

So they've got multiple kinds of studies where some might be an investigational drug and some might be an investigational device, some might be a drug that already exists, but they're utilizing it for a different label purpose.

So you've heard of the terminology off label. sometimes different drugs are used for off label. but that sometimes they might utilize trial designs that way as well.

So you might not have to if you feel like, gosh, man, I really want to take this drug, but I don't know if I can if I really want to mess with having to fill out that diary and, and jump through all those hoops, then there are options, typically within trial design.

So we've, we've painted a pretty, you know, serious picture of how regimented, trials can be. The complexities, but it's still very. Optimistic, as we've touched on that.

you know, we are being offered several trials. Every month, and we're just growing by leaps and bounds. It's very wonderful. To know that. There's that.

Kind of commitment out there to invest in neuroscience. Research. but I. Want to make I want to, you know. As we sort of wrap up this part of the interview and maybe just.

Touch on foundations a little. Bit, which I think can segway nicely. You know. There is a question with all of that sort of hassle. Why be in a clinical.

Trial in the first place? Why participate? Right. And I know that. People have different reasons. That they may choose to be in them, but I'm going to.

Highlight at least, you know, 2 or 3 of. Them. Sure. So we do get asked that question quite a lot. And whenever, whenever a patients are talking through their options with us, always, always.

And the things that we're doing is we're not trying to as a research team. And I think you often do that. You have a little bit more guidance as a physician.

But whenever they're asking us, you know, what should I do? That's not a decision that we can make, but for someone. But we can lay out the reasons. And a lot of the reasons that I tell them is the biggest and foremost reason is if you if you have something like Parkinson's or something like M. S.

or all timers, if you're in a clinical trial, then you are under an extreme watchful eye by our medical team, by the pharmaceutical companies, medical team.

We're doing labs, we're doing imaging, we're doing, you know, you're you have a 24 hour access to a physician to your health care. If you haven't, if you have a problem.

So I feel like that is one of the biggest, biggest things about being in a clinical trial is that you you have that availability. Not only that, but you also have access to, to, and new investigational products that other just regular people off the street, they don't have access to that.

Another thing that I always try to highlight is if you have dealt with insurance at all, then you know, the aggregation of trying to get things pushed through insurance.

And for some reason there are sometimes there are so many hoops and hurdles that have to jump through. But if you're a new person is diagnosed with M. S., it might take you three months before you actually get to be on drug, because you have to jump through all those insurance hoops.

And with clinical trials, you don't have to mess with that because there is no insurance. There is no you're paying out of pocket to do things. It's we're paying you to come.

We're paying you. We're giving you this drug that's provided we're giving you all of these, these tests for free. It's no cost to you. So that's always a big benefit to doing clinical trials as well.

So those are a couple of the big things that I that I highlight for patients. And then sometimes there are patients particularly we see this in in the all timers therapy area.

Is that their legacy. They're doing it to help people in the future so that they don't have to go through what these patients right now are having to go through.

They want to be a part of of hope. They want to be a part of innovation. They want to be a part of legacy. So there's there's many things that motivate people.

But those are those are three of the more prevalent that I see. Yes. That's perfect. I agree completely. I would say. Only, While there is. Compensation often for participating in a. Trial.

And that compensation may be. Just, a direct. Payment, or. It could be like a visa card that you get. Yeah. At any

rate. and then there's compensation sometimes for.

Meals, for travel, for. Transportation. this is not like you can make a living. Just like a clinical trial. So we don't want. People to think that it's such a large.

Dollar amount that, oh, man, I'm paying my mortgage payment. We write bills and things like that, but but by and large, there is. Some. Degree. Of compensation.

For participation. Pharmaceutical companies try to make it accessible for anyone that wants to be involved, where that's where the payment comes in, where, where that might be.

They might pay $55 for a visit. Well, that would cover your gap. Or if you live farther away or you have a visit that might take 6 or 7 hours, they'll provide meal compensation or they'll provide a hotel.

They they're not going to necessarily pay you directly on those things. They might help set that up for you, but it will. They do try their very best to make it accessible for all patient.

Now, because the. Parkinson's Solution Summit has a huge emphasis on. Therapeutic lifestyle factors. On understanding how you can make changes in your environment, and on implementing some of the principles of regenerative medicine.

So, for. Example, how. Hormone therapy can impact the brain in a very. Positive. Way and potentially. Slow. Parkinson's progression. I do want to. Be clear with folks that at this time I have.

And to my person, in my personal experience. I have yet to see a clinical trial protocol that says you. Can't work on your. Diet while you're in this trial.

You can exercise while you're. On this. Trial. You can't start hormone unless it's a hormone trial that you. Can start. Hormone replacement therapy. So what I like to say about what we do here is that our toolbox is really big because we do.

Everything that a good clinical neurologist. Hopefully anywhere in the world would do. We do all of the therapeutic lifestyle. Medicine, functional medicine, regenerative medicine.

Again, no country indication for the trial. And then we can offer a clinical. Trial. Participation. And you can do. Either or. Both. You know, it's not.

Like you're fixed. If you're in one bucket. You can't go to the other bucket, so to speak. Right? Right. They definitely go hand in hand. And I think some of that goes back to that positive mindset that we were talking about earlier with the if you approach it and you do everything that you can possibly do, you're going to set yourself up for the best outcome regardless.

Regardless. And another area I want to. Touch on that's super important right now. To us, as. Well as industry. As a whole. and I know that we can talk probably talk the whole a whole hour just.

On this alone. but that is that, there's a big push, a. Big concern. Really. and a. Desire to make sure that the population of individuals who participate.

In clinical. Trials really is a. Reflection. Of our. Country. Of the diversity. in our country, the ethnic and cultural diversity. yep. You know, and we're in the.

Midwest, folks. So, you know, I'm not. saying anything really surprising to say that. You know, this is a. Predominantly Caucasian area of the country.

I'm. I'm originally from new. Jersey, you know, very ethnically diverse. So I can tell. You that both the federal.

Government, in terms. Of the. FDA and the oversight of clinical. Trials.

Pharmaceutical companies, clinical. Research organizations, as well as individual trial sites. Right now. Have a huge, huge, push, a. Huge incentive. A huge, you know, desire.

And action steps. Hopefully in place to. Find, you know, subjects willing to be in. Trials who are maybe not just your average, you. Know. Average white guy.

As I am, you know, Which is okay. But I mean, in other. Words.

Diversity in Research and the Role of Foundations

We want African-Americans when Asian Americans, we want women and men, unless it's a gender. Specific trial, right? We LGBTQ, we want we want all we want all cultures.

We want to try to capture the footprint of everybody. we want to capture that same footprint in the clinical trial, because when we're providing data, it's only going to be as helpful as what it's encompassing.

And if it's only if it's primarily made up of 90% Caucasian, then you're going to find that it's not a robust data set. So it's kind of a it's kind of like the nature versus nurture sort of thing as well, because you might have a you might have a someone that has the same ethnicity in one, one population as, this other person with the same essence and another population, and they don't live their lifestyle the same.

So that could be reflected in some of the testing that's done within the clinical trial, which would change outcomes that on paper, you would look at it and you would say, okay, a 50 year old Caucasian male here, 50 year old Caucasian male here.

But if they they don't live their lives the same way, their data is going to present differently within the trial. And sometimes there. Are. For reasons that may not be completely understood, there are ethnic differences in the way that. People.

Respond to treatments, and that needs to be understood. Better. Correct? Correct. So we it's the goal to see every population, every culture as, as broad as we can represent it.

So, as we. Wrap up, one last question, you're an ambassador. To. The Parkinson's Foundation. we have. Parkinson's. Foundation president, you know, Michael J.

Fox Foundation. We have all kinds of organizations out there in support of Parkinson's. We have, sir, we I think you still do. On the Parkinson's. The Ozarks, advisory committee.

I've been their. Medical advisor for a few years. not as active in that group. But still retain, musician as their medical advisor on an as needed basis.

And, you know, these. Organizations play a number of. Roles. One of them is to actually. Support clinical. Research, but they do a lot. Of different things.

And we we certainly want to encourage. Folks affected, either directly or indirectly by. Parkinson's. To support these. Organizations and to seek them out and their own community.

So you can you just kind of broadly paint a picture of what. Foundations. Do. Sure. Yeah. So, the I've been an aware of Care ambassador for a couple of years now, and one of the best things that I've seen is the education materials that they provide and the initiatives that the Parkinson's Foundation provides to patients and even physicians and practitioners alike, that their mission is to provide as many materials as they possibly can.

One of the things that the Parkinson's Foundation has identified in that, in talking to their various control groups, is

that patients often are getting their diagnosis and they're they feel a little they they feel a little light, overwhelmed, and they don't know where to go when they they don't really know what next steps to take.

And the Parkinson's Foundation has done their very best, and they have outstanding material that's available for whomever, to help guide you through what to do if you get if you get hospitalized, what to do when you're newly diagnosed about Parkinson's and movement or and they have all kinds of kits and resources, they help you connect locally.

So you could reach out, reach out to your Parkinson's foundation, which is national, and they can help guide you to local resources like here in in our area, they would guide us to the Parkinson's, board of the Ozarks because we are the local board that that is connected to all of the Parkinson's things.

And, and, the Parkinson's Foundation does fund things for the local Parkinson's board or groups like, classes, music therapy, big step programs, all kinds of things like that.

Your Parkinson's Foundation and and your other disease foundations as well. I call Alzheimer's or Ms.. Those are always your go to and they can help you get set up locally.

And typically they will have an ambassador like me. That's an actual face that can help you navigate through any of the red tape. That gets to be overwhelming at times.

Absolutely. So let's folks. I just want to encourage you to not only. Support these organizations, but tap. Into. Them as well. They are there for you.

Our local, Parkinson's group, the Ozarks, Gives money to. Like you said, sport, music therapy, yoga, rock, steady boxing. Train, train, Practitioners.

In the Lee Silverman voice technique. all. Kinds of things. We put on. A5K run every year to raise money. so, please definitely. Check them out, support them in every way.

That you. Can, not. Just with your own dollars, but take advantage of the resources they have created for you or your. Loved ones. because these are really invaluable.

And at a time where. Too often we go to the doctor and it's. That five minute visit and they didn't answer my questions. And and there. May be only so much we can do to fix that.

Shortcoming of the. System, but the right things can. Help fill in some of the. Gaps. That's what they're there for. And they have programs within programs that are designed to help make that less painful, for sure.

Yeah. Well, Shauna Tyndall, I really appreciate your time. That's one of the things that really, truly one of the most informative interviews of the entire summit.

So I'm really pleased. Wonderful. I hope everybody, gets to listen. To it and take some notes. And honestly, if you do. Have any, questions about clinical.

Trials. That we can. Possibly help out with. I want to. Invite folks to, check out if that's okay. Definitely love to hear from people. at the risk of exploding your email box, do you mind sharing, sharing an email address?

Not at all, because I'm going to give you the research@sharlinfxmed.com the research R E S E A R C H S H A R L I N F X M E D. COM And if you happen to. Be.

Within, say, a two. To three hour radius of Ozark, Missouri. And you're interested in exploring clinical. Trials with us, we'd love. To sit down with you and.

Talk about what's available, and we'll, you know. Is coming very soon or what's currently enrolling, and see if.

There is a good fit for you. Definitely.

We'll we'll talk. Soon, I'm sure. Thank you. So much. Thank you. Bye bye.