Announcer: The HD Insights Podcast is brought to you by the Huntington Study Group. The Huntington Study Group is a nonprofit research organization dedicated to conducting clinical research in HD, and providing critical training on HD to healthcare professionals. Funding [00:00:30] for this podcast is made possible through the generous support of listeners like you and sponsorship grants from organizations like Genentech, Teva Pharmaceuticals, Neurocrine Biosciences, UniQure, Vaccinex, and WAVE Life Sciences.

Kevin Gregory: Hello, and welcome to the HD Insights Podcast. I'm Kevin Gregory, and on this episode, we talk with the study site coordinators at two of the KINECT-HD study sites about their experiences on the study so far, and about what they've experienced working with patients on clinical trials in [00:01:30] Huntington's disease over the years, including the importance of retention to ensure all new potential treatments are able to be fully and properly evaluated. Amy Chesire joins us from the University of Rochester site, along with Greg Suter from the hereditary neurological disease center in Wichita, Kansas.

On a previous episode of the HD Insights Podcast, we spoke at length with Dr. Dietrich Haubenberger from Neurocrine Biosciences, the KINECT-HD study sponsor. As a quick reminder, [00:02:00] KINECT-HD is a phase three, randomized, double blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of Valbenazine to reduce chorea associated with Huntington's disease. The study is being conducted by the Huntington Study Group at 46 total study sites in the United States and Canada. If you're interested in learning more about KINECT-HD, you can visit the study website at www.kinect-hd. [00:02:30] org. I'll provide that again at the end of this episode. And now, here's my conversation with Amy Chesire and Greg Suter.

All right. Well, welcome back to the HD Insights Podcast. We're talking about the KINECT-HD study. I'm now joined by two very experienced, long-time clinical trial study coordinators, Amy Chesire and Greg Suter to get their perspectives working with and [00:03:00] enrolling participants not only in KINECT-HD, but for clinical trials in general. So, my thanks to both of you for joining the podcast today.

Amy Chesire: Thanks for [crosstalk 00:03:14].

Kevin Gregory: Before we get into specific questions, I guess we'll start, let's start with Amy. Amy, can you just tell the audience a little bit about yourself, your role and your research site?

Amy Chesire: Sure, yes. Well, I'm Amy Chesire and I am based [00:03:30] here at the University of Rochester, which is in upstate New York. And I have been here at the university for almost 29 years now, which is a little hard to believe. And we are a HDSA Center of Excellence taking care of folks that are dealing with Huntington's. So my background is as a licensed clinical social worker and [00:04:00] family therapist, but I'm also a clinical study coordinator and have been a coordinator for a couple of decades now. So it's a nice mix of trying to

help people to be involved in research, trying to find answers to Huntington's, while also trying to take care of people that are everyday just trying to deal with this disease.

Kevin Gregory: Great. Thank you. And Greg, how about a little introduction about yourself [00:04:30] and your site as well?

Greg Suter: Okay. My name's Greg Suter. My title is executive director of Hereditary and Neurological Disease Center. We're based in Wichita, Kansas, right in the center of the country. So we serve a regional area. We just work with Huntington's disease, and we're a free-standing, a non-affiliated with a hospital or university. We're a free-standing non-profit [00:05:00] entity that uses a volunteer medical team and provides a multidisciplinary approach to managing Huntington's. I've got a little seniority on you, Amy. I've been at 30 years. So, a lot of the families that we see, I've seen generations [inaudible 00:05:23], and we started with just diagnostic services [00:05:30] and somehow we're invited to participate in the research studies, and I've done many, many, many studies. And so I wear the badge of lead study coordinator for the majority of them.

Kevin Gregory: All right. Well, it's great to speak with both of you and get your perspectives on these things. So Greg, I'll stick with you for a minute and start here. I know your site actually enrolled [00:06:00] the first patient for the KINECT-HD study before COVID-19 hit the world. So let's start there. How have things changed for you in that time, where you've had to implement things to make the study enrollment and site visit process safe for participants?

Greg Suter: Well, when we started in 2019, there wasn't COVID that was known [00:06:30] as it is today. And so we had four people in the study, and they actually successfully completed the first phase of the study, but weren't allowed to go into the rollover because of COVID. So, the first group of four really weren't affected by the COVID processes, but then we enrolled two additional subjects. [00:07:00] There was no way really to monitor that the labs, they weren't willing to go to a private lab. There really wasn't in the processes a means to do that. And so they were withdrawn from the study, [00:07:30] and we rode COVID out through the summer until it opened back up again.

And then those two that had early termination visits in KINECT-one were allowed to move into the rollover. And so three of the original four and those two then were the first KINECT-two subjects we had. But it certainly was a different process than what we [00:08:00] had with the initial enrollments. A lot of temperature taking, a lot of mask wearing, a lot of travel concerns, hotel concerns for those who stayed over. Certainly it was, for everyone involved in studies or just medical care in general, it was a unique time. So, we implemented processes, we talk with other people. Our offices [00:08:30] are part of a large medical park, and so we relied on some of the other entities to model what we were going to do as far as moving forward with allowing in-person visits.

Kevin Gregory: All right. Well, and Amy, same question for you is, is that a similar experience? Is there anything different that you had to do, or your site had to do because of COVID, or are still currently doing, and how has that [00:09:00] even evolved now that more is starting to open up and more people are getting vaccinated? I'm curious, how that's changing as well.

Amy Chesire: Yeah. Well, we were a little further behind, Greg, certainly in enrolling our first person into KINECT. And so when COVID really got started here, [00:09:30] by mid-March, I would say, we had two people that were in the early phases of the study. And then we got hit with a pretty hard pause, I guess, was the word that was used. And because we're part of a larger academic medical center, we had to obviously follow the guidelines from here, which essentially almost all [00:10:00] research operations were told that they needed to stop doing that except for our COVID studies. So I think the thing that, and like similar to Greg, then we had a similar timeframe and eventually got started back up, I think, around July, end of July, or maybe early August.

And I think the thing that I found challenging, well, there are a lot of things, but related to the study was so [00:10:30] many of our HD folks were really concerned about this negative impact on research, and so it was a lot of trying to continue to support our participants, and let them know that we're working with the study sponsor, and we are really trying to... don't lose faith and hope in us that we're going to be able to resume the trial. So it was really keeping some [00:11:00] hand-holding going, some support going, that there was going to be some degree of light at the end of this tunnel, and that we would be able to get people back in. And thank God that definitely was the case.

And like Greg said, then once we did get that green light, everyone was so thankful we had... It was a new place around here. It was still very quiet. We had to reduce our overall [00:11:30] how many people we could have in the waiting room, the size of our exam rooms, a lot of things to the physical plant to try to really maintain that safety. And so I think all of that's become really important and continue to be important. And it's amazing, as I always say, and I know Greg knows this, the perseverance of people that are dealing with Huntington's, in some ways, Huntington's [00:12:00] is a much bigger lift than COVID perhaps.

And so I think people bring that resilience with... And also when it comes to research that they really did. So I think it's continued to be inspiring. We're continuing to keep with the safety precautions. Now it's nice to see people when we ask any new medications hearing, oh, I just got my vaccine last week, and to be able to put that on a [00:12:30] medication log is really, pretty inspiring and nice to see happening.

Kevin Gregory: Yeah, I would agree, and I think that makes a good segue to the next logical question, which is, you mentioned that uplifting feeling or spirit about being able to continue with the study or participate in research. Can you talk about that for a little bit? So, aside from the potential benefits of the treatment itself, [00:13:00] clinical trials have these other tangible benefits for participants.

What are some of those other positive participant experiences that you've seen over the years, or in this study, just as a result of people being enrolled in research?

Greg Suter: Yeah, I can start and then you... You can add or interrupt me at any point in time. I am the dinosaur [00:13:30] within the HSG, because I've been with it so long. And I come from the age when there weren't studies in Huntington's disease really being done. There was no Huntington Study Group when I started. So, back in the day, we had DNA banking and we had brain tissue donation. Those were the research options. And [00:14:00] everybody that came in was like, what can we do? What can we do for research? What can we do for research? Then PHAROS came along and a myriad of other studies one after another. And from the person participating perspective, they're very selfless. They're not doing it. I think I would be more selfish and say I'm doing it because I want it to help me, but they really... [00:14:30] I can't think of anyone to give an exception to. They all want to do it for everyone who has Huntington's disease and for generations to come.

That's why they're participating. And I hear it over and over; well, it's probably not going to help me, but if I can help somebody else, and this is from people who don't have children, so it isn't always, I want to help my kids or my grandkids. They just want to do [00:15:00] what's right for the greater good. And I think maybe it's not unique to this population, but because it's a genetic disease and it's a rare disease, they get that there aren't that many people out there to help. And so it's important that because of the limited number of participants that they step forward. And [inaudible 00:15:23] all of them all the time the travel that they do. They [00:15:30] drop everything and come to a visit because it's the only time that's available to them around the holidays or whatever it might be. They're just very vested. And whatever research option that is there, be it simply the observational studies that are going, or if it's a clinical trial.

Amy Chesire: Yeah, I would just to piggyback on that. I am, even though I've been at it a while, I am still [00:16:00] really amazed what I perceive as like can be quite burdensome. There are pieces of the clinical trial, whether it's MRI scans that are done, or receiving an infusion, that I see are terribly burdensome. And I'm constantly amazed when I'm projecting there because when I check in with people, more often than not, [00:16:30] I'll hear, oh no, it's really not that bad, oh, I was in the MRI scanner for 40 minutes, but, you know, it wasn't really that bad.

Or I have to drive, like Greg saying, three hours each way, maybe in the middle of a raging winter storm here in upstate New York and, no, you know. And so it's just, I think that keeps us all going, is like our perceptions of the burden, versus [00:17:00] what people living with HD are often maybe not quite the same and it's super inspiring.

The other big thing that I often certainly notice and become aware of is that, and I often say this when someone's thinking about joining a trial who's never been in a clinical trial, in particular a drug trial, is that there is so much more to it than just the drug. And it doesn't take people I [00:17:30] don't think too long before they're participating that this becomes obvious. One, you are, you get to be on a pretty set schedule here of when we're expecting to see you, what the visits going to kind of be like. So you're a lot of additional support from our end, I hope, and I think that really provides dividends to [00:18:00] our people that are living with Huntington's disease.

It's hard to often quantify some of those things, but a lot of these secondary gains that people... And even when people come to find out quite a bit after a trial's done and we tell them, yes, you were on placebo or, no, you had been receiving the drug. At the end of all of that, it's just the people [00:18:30] got so much out of just trying to make a difference, feeling like something can be in your control when a lot of things related to HD sometimes aren't.

Kevin Gregory: Yeah, those are all really great points. I wanted to circle back to something that Greg mentioned and for both of you to weigh in on, and that was about the willingness of the HD community to participate in research. Greg [00:19:00] described as being selfless, wanting to benefit the good of the community. And I bring that up because one of the... what this trial's main endpoint is, is a study of Valbenazine for treatment of HD chorea. And we know there's two FDA approved treatments for chorea out there, but not all treatments are the same, and there's some really valid reasons for studying further treatments. And I'm just curious from your perspective, [00:19:30] have you had that conversation with folks? Do they ask the question about, well, why should I bother with this study? Why is it important if we already have these tools available?

Greg Suter: Amy, you want to take that?

Amy Chesire: Yeah, it's funny, I don't often get asked that question quite honestly, which I'm not sure exactly what that means. [00:20:00] I generally, I approach it more, usually I'm asked, what kind of trials do you guys have available right now? So it's usually more in the position of just overall explaining, and usually we're blessed to have a couple of trials going on at any given time, so that we can really present it to someone, these are the available options, [00:20:30] here's what might be a good fit for you, or maybe for these reasons, this trial isn't a good fit for you.

So, I think it's more, that I tend to come at it from that point instead of necessarily really having to justify. I think the Huntington's community, like Greg was saying, is remains just so grateful that there are these options that are [00:21:00] being explored, that there isn't one just totally perfect drug to help manage chorea. So I think folks keep a pretty open mind and are more glad that a pharmaceutical company is trying to put on this big trial, and often really then want to step up to try to help out.

Greg Suter: I would add to what Amy said, we really don't have people ask, why should [00:21:30] I be in this study when there are already drugs that exist to help with movement associated with chorea? It typically starts as a conversation with, are there any research studies going on that I would be interested in? Or a spouse or a child, or even a parent, in some cases, asking, is there anything that, they want to participate, is there anything available? [00:22:00] And that opens the door to the discussion. And in the Valbenazine study, the KINECT study, you can't have been on another drug for movement; the tetrabenazine or [inaudible 00:22:19] or Austedo to participate. And it's certainly limited the number of people available for the trial, and [00:22:30] we see just, we only see Huntington's at our site.

So there is no lack of numbers. It's who makes the best participant in the study. We had people that travel 14 hours. Would that be a good participant coming every two weeks? Probably not. But we certainly give everyone the option to participate who wants to participate. And so we don't need to have the discussion of, if there are [00:23:00] other drugs, why would I be on this one? It's, again, more like, well, if with the drug company thinks it's viable and you think it's viable, then we're interested. Tell us why you think it's viable. And the conversation then goes down the path of the current drugs sometimes don't work for people. And so there is room for another option that particularly may work for someone if the drug is approved by the FDA.

Kevin Gregory: [00:23:30] Right. Yeah. I really appreciate your insights on this and the type of perspective that folks bring to these questions. So let's follow on and move from there, which is, okay, what trials are out there? What research is available to me? Somebody, you explain what's available and someone says, I'm interested in participating in this. What is the sequence of events that happens next [00:24:00] in terms of their role, your role as a study coordinator, up to the point of enrolling somebody in the trial?

Greg Suter: Amy, you want me to go, or do you want to go first?

Amy Chesire: You can go first. I imagine there may be some differences here, so you start.

Greg Suter: Okay. So, usually starts with a phone call, because we're scheduling them for another visit [00:24:30] or scheduling a relative, or had recently scheduled a relative for a visit, and then they shared that there's research studies. The one thing that is impossible to keep undercover in the Huntington's population is what's going on in research. They're very on it. I'm amazed at how much they know. Sometimes before I even have confirmation of things, they know things, [00:25:00] because they have a lot of time to study it.

So if somebody calls and says, I understand that there's a study and do I qualify, and they're planning to come for an appointment anyway. Then I do what I all is a pre-screening, because with all studies, there's inclusion criteria, there's exclusion criteria. You don't want to have someone come just from a study visit and then find out after they've [00:25:30] traveled hours that they don't meet

the criteria. So it isn't very time intensive to do a quick check, and especially we primarily see people that we have a history with.

It's better for retention, it's better for visit reliability. If we know that they're regularly calling us to schedule [00:26:00] appointments and they don't miss appointments, and that they have been in other studies perhaps previously, they're good candidates for another study because you have a history with them. So, using that information and checking... There's so many things to check; medications, their BMI index, are they too [00:26:30] big or too small? Are they too old or too young? What medications they might be on that would exclude them in the case of KINECT, if they were on Austedo or tetrabenazine or [inaudible 00:26:46]? That the idea of being, give them hope that they may in screening make it through the process. We don't know their lab will be, we don't know what their EKG might be. [00:27:00] But everything else should be pretty much determined before they ever step foot in the door with pre-screening subjects.

And I know not everybody can, and it's just because we have the large database that we do that we're able to pull people when the study starts, and I don't know how much you want to go into the site interest form. But [00:27:30] we're required to submit a questionnaire of how many people do you have that fit the study? How many studies are you doing that might conflict with enrollment? Do you think you can enroll... A lot of those kinds of questions. And you have to take all of those into account and it's... It's the role of study coordinator to do the best job that you can [00:28:00] get the best candidates for the study who have a history of good retention for visits, and are good candidates, which is, again, why we predominantly utilize people that are already in our database, as opposed to somebody who would call and say, I hear your site. Can I be in the study? We wouldn't exclude them, but the process is a lot different.

Amy Chesire: Yeah, and I'll just, to chime in. We may be a little [00:28:30] bit different. We tend to, when we have our HD clinics during the month, we tend to often pull people that are actually right there at their visit who have expressed interest in research and participating. And then I can really usually often be able to talk with them, give them a sort of an overview [00:29:00] or a lay of the land related to the study. I usually then send people home with what's called the informed consent. And the informed consent is the Bible of a research study.

It's often, I think for KINECT, it's over 30 pages long. It goes into every aspect of the study. But it does really, it's [00:29:30] kind of does our due diligence to really folks can at their leisure then take home, look that over. And then usually I'll do a follow-up call a couple days later to see what their thoughts were about that, and whether or not it seems like something they might be interested in pursuing. And then we generally, like Greg said, would set up [00:30:00] a screening visit, and the screening visit is really the opportunity for us to figure out whether someone's going to be a good fit for a study like KINECT.

Like Greg was saying, I always say, there's things we want you to have and then there's other things we don't want you to have to be part of a study. Some of that we definitely can know ahead of time, who's going to probably be a good fit. And then some of those unknowns that we won't know until somebody actually comes in for that [00:30:30] screening visit. So, I think that's there's all the sites across the US I'm sure do things a little bit in their own unique way based on their population.

Announcer: We'll return to the interview on the HD insights podcast in a moment. We hope that you're enjoying this episode. As a nonprofit organization, the Huntington Study Group [00:31:00] relies on the generous support from the community and listeners like you to continue bringing you in-depth content on HD like this podcast series. If you like what you're hearing and are interested in supporting HD Insights through a grant or donation, please contact us through our email address info@hsglimited.org, or by calling toll free at 1-800-487-7671. [00:31:30] We greatly appreciate your support. And now, back to our episode.

Kevin Gregory: Yeah. And you both touched on points that I want to circle back to in a moment regarding fitness or being fit for a particular study. But one thing I did want to ask both of you, if it's come up because that's around anosognosia or [00:32:00] what's referred to as the lack of awareness or acceptance around chorea, the issue being that somebody with chorea that may be impacting their quality of life or what they can do, they don't necessarily recognize that. Or maybe think that's an issue. I'm just curious if, whether it's with the study or just in other clinics settings, how often or what that conversation is like with someone about [00:32:30] their chorea, if they're showing this maybe lack of awareness around it.

Greg Suter: Amy, I'll jump in, and be short with it. The majority of people we see acknowledge some degree of chorea. If they had no chorea established that they would come to see us unless they were in an observational study [00:33:00] trial. And they would not be diagnosed, which would be exclusionary. You have to be diagnosed with Huntington's to be in the study. So we don't see a lot of the lack of awareness to getting them in the study. What is interesting is that the ones who are in the study, their perception of their chorea is a whole lot different than [00:33:30] the clinician's impression of their chorea, which is the acknowledgement of symptoms. And I find that's always been fascinating, because people will say, do you think I have a lot of movement?

And I always ask the question right back. Do you think you have a lot of movement? Well, I have some movement. I have a little movement. And then usually whoever comes with them [00:34:00] makes the correction. So that's the right term. It's like, you don't have a little chorea, you have a lot of chorea. Be it a child, a parent, or a spouse, sometimes even a sibling. And it doesn't convince them that they do, but it provides an awareness that they do, then they shrug it off. It's like, Oh, well, it really doesn't bother me. So, maybe I just don't know about it. But it is an interesting component to, and I think for some, it is an obstacle [00:34:30] in enrolling in a drug trial that involves movements. The

chorea associated with Huntington's disease, because there is a denial of the severity of symptoms. I don't think that we see a lot of people who deny symptoms 100%.

Amy Chesire: Right? Yeah, no, I agree that, I think this can sometimes [00:35:00] be a little bit of a tricky area and clinicians that take care of folks with Huntington's I think probably have a lot of different opinions about this. Historically, what it was only maybe 10 years ago now when Xenazine first came into the story, and that was really by HD families. I remember at that FDA hearing [00:35:30] really going to bat saying we need something, we are desperate for something. And so there's certainly, it was a long time in coming to get that first FDA medication approved, and to see where we're at now it is really inspiring. And way back then maybe because we didn't have options, we probably didn't quote unquote, “treat a lot of chorea”, per se.

[00:36:00] And I think obviously more of that has shifted with having treatments available. Obviously move the curve there. I think we try to stay with where patients are at on this one. And like Greg says a lot of times, families will perhaps be a little bit more aware and cognizant of the impact of chorea that other folks can't. I had a woman who, for [00:36:30] example, she works in a County jail and she has Huntington's disease. She was a new patient here. She came along with her two sisters and she was interested after she saw us in participating in this trial.

She didn't really think that she had much in the way of extra movements, that's what we usually call it around here. But her sisters, as [00:37:00] we're talking more to more about her day-to-day job, they're sitting next to her a little behind her with a lot of this shaking their head. Like, we think your movements, the sisters also work in the same system. So they're very aware of things. You could really see how her chorea, even though it wasn't by no means profound, but significant enough that it was making it harder to lock things up, unlock [00:37:30] things, she had a lot of hands on with different folks there. And so sometimes I think it is trying to get the whole picture of what's the impact here for people's chorea?

Kevin Gregory: Sure. And, I know every clinical trial is different for the study visits, but in terms of KINECT-HD, what is a typical study visit like once you're enrolled in the trial, [00:38:00] what does that involve for participants?

Amy Chesire: Do you want to Greg? I think in general, once you get those big visits, which is usually that screening visit, and then that second visit, which is what's called the baseline visit, and then that's when people are actually dispensed study drug to get started on it. Those visits tend to be somewhat lengthy because we're gathering a lot of new history and data [00:38:30] and a lot of different procedures that are going on. But I think after that, the subsequent visits, they are frequent like Greg was talking about. Every two weeks is a little bit of a lift. But it doesn't go on for a long period of time, every two weeks. So it's kind of a

more frequency, but overall shorter duration of the double blind phase of the study.

[00:39:00] And so I think all those visits after the baseline, we tend to try to be very aware of people's time and their commitment and try to move through a study visit, reasonably well. Sometimes we'll hit some hiccups along the way, but at least on our end, and again I know there's probably a lot of variability, but generally they're about hour and a half I want to say in duration, an estimate from start to finish. [00:39:30] So just to give people I think a ballpark idea. And then again, once you hit the end of the study, then the visits take longer when you get into those final phases of the first part of the study.

Greg Suter: And I pretty much ditto what Amy just said, as far as the visits go. It's interesting because when you talk with people in the consenting process, or even the pre-screening process, [00:40:00] they want to know how often they have to come. And for this study, they come every two weeks for 14 weeks and then rollover. And they're on the other placebo or they're on the drugs. During that period of time were blind, the investigator is blind, everyone is blind as to what group they're assigned to. And as the visits progress every two weeks, they [00:40:30] start to try and get you to tell them what you think. And you as a clinician, you have to be blind to all kinds of effects. One is I think I'm on the drug, what do you think, kind of questioning.

And what is really interesting in this study, because of COVID versus the Austedo study, the first [00:41:00] stage D study is that we have to keep the participants separated to a good extent because we can't have them all in the lobby at the same time. In the first HD study they became friends. We had people who even traveled with other participants in the study and they would talk about what they thought they were on drug or not on drug, or various types [00:41:30] of components, but they built relationships. It was an interesting support group. And with KINECT because there's the social distancing component, as soon as somebody comes in and we pre-screened them on the phone initially for COVID, tell them they have to wear a mask when they come, check their temperature upon arrival. And then we put them in an exam room and they stay there until we moved them.

[00:42:00] And there is no real opportunity. They may see someone going to the restroom or coming in after them, but there isn't an opportunity for really an engagement of, do you think you're on drug? And that's unfortunate because I think the bonding that took place with the other studies we've done is the camaraderie of the people, not just the people with Huntington's, but the people as companions that bring them. So [00:42:30] that the uniqueness of the timeline we're using now is unfortunate because they don't have the opportunity to query others. It's like, do you think my movements are better? And that may be even a good thing because they're not given the false hope that, Oh yeah, I think that your movements are a lot better, by someone who doesn't know what their movements are.

Kevin Gregory: Yeah. That's a really interesting [00:43:00] observation and it'll be interesting to see how it plays out as well in the end and compared to future trials after this. I really appreciate the time both of you have provided for this. I want to wrap with just one more question for the two of you, and it's something that you brought up in an earlier response, making sure you get the right participants for a study, for any study. Retention is always the key to the success of a clinical [00:43:30] trial. What is a conversation that you might have with a participant where either they're unsure if they'd be able to complete the study or they're having second thoughts about staying in or considering another study that's coming up simultaneously? What are some of the conversations you've had around retention with participants over the years in your experience?

Amy Chesire: Yeah, I can take a [00:44:00] stab at that. Yeah. Especially, I think when someone is participating for the first time in a clinical drug trial, one of the things that I do is really try to explain the difference between being a patient and being a research participant, because most folks really don't understand that distinction. And it is important that they understand [00:44:30] that, when you're participating in research, it's much more of a one-way street in many ways. In other words, we're gathering a lot of data from you with what you're experiencing while like in this case being on Valbenazine or taking placebo. And so there's not as much of that give and take. And so, like Greg was saying, it sometimes can be a tricky because people start asking you those [00:45:00] questions or, I think my motor exam went better this time than last time, what do you think?

And that kind of thing, which is totally normal and natural curiosity to ask. It's just when you're in a trial, we have to maintain our objectivity about it. And we don't know whether somebody is on drug or not ourselves. And so I think, really trying to bottom line, I don't want people [00:45:30] to be surprised by what goes on in a study. So trying to minimize the surprises or the, oh, well, you never told me that, or I didn't understand it was going to take that long, or I can understand I'm going to get my blood taken at every visit. I think we really just really want to try to help people feel well-informed, but they know what the trial is about what the commitment is about, and not everyone's [00:46:00] up for making that commitment and that's perfectly fine.

I think people have to know that. I'll often say, maybe this trial isn't a good fit for you, but there will always be another trial going on. And so, we're going to have the best luck with keeping people in the trial. I think as long as we can be as transparent as possible about what the expectations are, what the things you can [00:46:30] really expect to go through with the trial as best we can. So I think being as upfront really can help a lot with keeping people in a trial.

Greg Suter: I would add to that Am, everything is in the consent and the consent process for the study, and there's nothing more important in the study [00:47:00] than the consent process. It would be easy to just say, Hey, here's the study, sign the paperwork, but it doesn't work that way. There's the capacity process to see if they can and are able to sign on their own. Do they understand the study? Then

going through page by page, here are the options. And in the KINECT consent, it has numerous places where it says, and you can [00:47:30] withdraw without any effect on your future care. You can withdraw, you can withdraw. Because if it's part of the process you're not contracting for anything. While at the same time, we don't want people who come into the study and it's like, well, it just wasn't a good fit for me, so I'm going to leave.

So I always just take it a few extra steps. And [00:48:00] if somebody is questioned as to whether or not they really want to participate, say it's a commitment, yes, you are able to withdraw at any time. But if everyone withdraws from the study for one reason or another, or jumps to another study because they think it might be better or whatever they might have read on the internet, axe the study. And so I just try to encourage them to, [00:48:30] for the period of time the study exists, stay the course. But know you have the option of leaving, but make it a little more of a commitment [inaudible 00:48:44] participant as opposed to, well, if something better comes along then is it okay that I leave, kind of conversation. And so I just, again, from the get-go and Amy, you said [00:49:00] just being transparent and I think good consenting provides that transparency.

Give it to them ahead of time, let them read it, let them scribble their questions on the form, then bring them in, answer their questions. One of the concerns that I always have is when the caregiver says, I want them to participate in the study. And when you ask the individual who is going to be the subject in the study, [00:49:30] if they want to participate, if they respond with, well, my wife thinks it would be a good thing, then we go back a few steps and then engage their interests. They have to be the one entrusted. And, I'll just ask to have the person in the room alone and really get their thoughts on, you want to be here, or are you here because someone else wants you to be here? And I think that's another [00:50:00] important component in getting good retention and people who participate through the end of the study.

Kevin Gregory: Amy and Greg, you've brought some really fascinating insights to the conversation here today for us. And I appreciate your time and just want to thank you for joining us again, sincerely.

Greg Suter: I want to thank you, Kevin. And I want to thank the population [00:50:30] that is Huntington's disease, for their amazing energy and interest in studies.

Amy Chesire: Yeah. I would second that all of the… we couldn't be here and do this work if it wasn't for our HD families who are really at the heart of all this, but having all the structure around them, whether it's the Huntington study group or Neurocrine, who's sponsoring the KINECT trial, [00:51:00] it really does take a whole community here to do this. So thank you.

Kevin Gregory: My thanks again to Greg Suter and Amy Chesire for making time to speak with me on this episode. Once again, if you would like more information about KINECT-HD, you can visit the studies' website www.kinect-hd.org. That's spelled

K I N E C T [00:51:30] dash H D.org. And a special thank you to you, our audience for joining us once again on the HD insights podcast. Be sure to subscribe to the podcast to automatically receive the latest episode releases as soon as they are available. Until next time, stay safe, be well, and look out for one another.

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