Biogen Inc.

Biogen Inc. presents at Financial Times: Decentralised Clinical Trials in Focus

Tuesday, September 26, 2023 10:00 AM

Event Participants

Attendees 4
Donato Paolo Mancini, Angela May, Harpreet Gill, Stephanie Manson Brown

Executives 1
Jane Twitchen

Donato Paolo Mancini Attendee

[Audio Gap] a house here in Central London. My name is Donato Mancini. I'm a reporter at the Financial Times. I write about health and pharmaceuticals. We're going to hear today for this event titled Decentralized Clinical Trials and focus on overcoming challenges to drive economic value in clinical development.

It's an event that we're holding in partnership with ICON. We have a star-studied panel that is going to discuss a couple of hot issues in the sector with us in just a moment. But before I do so, I would like to remind you that you can ask questions. We love your questions, and we'll be sure to save time at the end of the event to ask some of our panelists. You're more than welcome to share any thoughts that you might have on the content of the discussion on Twitter using -- well X, formerly known as Twitter, using the #FTHealth.

And if you would like to do that, you can head over to the community chat to have discussions with other attendees. Again, we want your questions. We love your questions. It keeps our panelists engaged and then make sure that we can help you -- we can help answer any questions you might have. I'm going to ask my panelists to introduce themselves very briefly, and then we'll move on to the discussion.

So Angela, would you like to start?

Angela May Attendee

Thanks, Donato, and thanks for having me on. I'm Angela May, Head DCT Strategy & Implementation at Bayer in Clinical Operations. And my team and I work directly with project teams to develop and implement their DCT strategy as well as helping to develop the broader organizational capability and infrastructure for DCT.

Donato Paolo Mancini Attendee

Thank you so much. Jane?

Jane Twitchen Executive

Hi. Good afternoon, everybody. Thank you very much for having me here today. So my name is Jane Twitchen. I head a group at Biogen called the Clinical Trial Accelerator unit.

And we have a number of sub-functions within that group, spanning everything from feasibility to clinical trial diversity and including DCT along the way, very similarly to my colleague at Bayer. We work across the portfolio, defining our strategy, selecting vendors and ensuring that we do everything possible to be patient-centric in our approach to DCT. Thank you.

Donato Paolo Mancini Attendee

Thank you so much. And lastly, Harpreet from our partner, ICON.

Harpreet Gill Attendee

Thank you, Donato. So I am Harpreet Gill. I head up the decentralized clinical trial solutions team here at ICON. And not dissimilar to my panel members, I do have responsibility for driving DCT strategy and operational delivery at ICON. And as the partner for this session, I am going to tee up some of the questions.

So if you wouldn't mind popping up the slides, I'll just run through some of the topics that we want to discuss today. So initially, I think what we want to talk about is our recent experience of decentralized clinical trials and where we're seeing some of the greatest benefits and how these are influencing the decisions around implementing decentralized components. And then there are challenges. So we do want to discuss some of the technical and operational challenges that we see and how perhaps there can be real significant barriers to adoption, how perhaps we can overcome some of those barriers. And then we can't forget regulatory guidance.

It's really important that we have enough clarity and confidence to proceed with DCTs, particularly using novel methodologies. So do we have enough clarity, what are the thoughts on the regulatory guidance we have in place to date. And then we do want to look at some of the fiscal impacts of decentralized clinical trials and understand what some of the underlying evidence might be out there in terms of what the outcomes are compared to traditional trials. And then finally, let's see if we can talk about some of the ways that we can measure the economic value of decentralized trials and see if there are any emerging trends in that area. So that's it from me to tee up.

I'm going to hand over to Donato and I see we have other panel members on camera now. So hopefully, she can join us.

Donato Paolo Mancini Attendee

Thank you so much. Hi, Stephanie, you made it.

Stephanie Manson Brown Attendee

Hi, everyone.

Donato Paolo Mancini Attendee

It's wonderful to have you here. So we just started with the introduction, so you came in at the right time. Would you like to briefly introduce yourself and then we'll get started with the conversation.

Stephanie Manson Brown Attendee

So hi, everyone. We've had some last-minute technical challenges. So we're talking about decentralized clinical trials and technology. So very topical issues that I've been experiencing. So I'm Stephanie Manson Brown.

I'm Head of Clinical Development and Scientific Innovation and Vice President at R&D for Allergan Aesthetics at AbbVie, and I'm delighted to be part of the discussion today.

Donato Paolo Mancini Attendee

We are so happy you could join us. There was a risk. We thought for a second that you might not be able to, but we're very happy you are here. Let's -- I want to remind our audience that we love your questions. There should be space on the right-hand side of your screen to submit these questions which will then make it to me, and I will be sorting them to put them to our panelists.

So please, please ask [away.] So let's start the conversation with. Obviously, decentralized clinical trials are incredibly and fortunately hugely valuable for certain parts of the industry, also for patients, they made a huge kind of [explore] during the pandemic for obvious reasons. But I would like to ask my panelists, what have your experiences of clinical -- of DCTs has been like in the past year and -- in the past few years? And where have you seen the kind of the pros of DCTs emerging?

And how are you holding these in mind when you make decisions in the clinical space or the regulatory space or whatever space? Why don't we start with Angela, and then we'll move on.

Angela May Attendee

It's funny actually, Donato that you mentioned the pandemic because I think there's really 2 camps there. I think some people really think that they held us back as opposed to pushing us forward. And I think -- myself, I think it was a double-edged sword. But what we've really seen now is rather than the whole help we need business continuity in crazy times to actually, we've seen that life can be more flexible. So why not clinical trials as well.

So with the teams that we're working with, we've seen a lot of really good engagement.

People really wanting to change things to modernize things because recognizing that we can't stand still with our conduct and that it really needs to get a bit better. So we've seen a lot of engagement from our teams, which is what we've really needed to explore approaches in studies. And yes, we've had some quite -- well, we're still on the journey, but we've had some

interesting findings so far.

Donato Paolo Mancini Attendee

Well, could you give us an example?

Angela May Attendee

Yes. I mean we -- so two of our -- actually, all of our studies are Phase III. So it's a bit of a slow burn. But we've -- two of our studies, we've really managed to pull out some metrics, which anyone in the space will know that we're obsessed with metrics in clinical trials, but pulling them out for DCT was a bit easier said than done. But we've managed to get some preliminary metrics out of some of our studies, and we've seen that maybe some of these promises for supporting recruitment and retention and diversity, actually, maybe that's true.

So we're seeing some early signals that, that really might be the case, which is really, really exciting.

Donato Paolo Mancini Attendee

Interesting. And Jane, what about you?

Jane Twitchen Executive

Yes. So we're similar to Angela that we've had some exposure to DCT in a number of trials now. And we've kind of got 2 extremes. So we've had real success on some non-interventional natural history trials that we've done in a completely diverse fashion. So we've done a collaboration with [indiscernible] study, where we've used the iWatch, Apple phone, et cetera, for collecting some data about patients cognition, brain changes as we go about our daily life.

So that's been fascinating and really exciting. The data there has been really useful. We've also done a completely decentralized childhood epilepsy study, which is very much about putting the patient first and really minimizing the impact on these incredibly ill patients lives. More often than not, though, we're looking at small elements of the protocol. So is there a part of the study that we can deliver in a decentralized fashion.

One study that brings to mind that we started recently is for a rare genetic condition. And the patients that we're bringing into the trial on, they're not even patients, they're presymptomatic gene carriers at the time the study starts.

So we wanted to make that running period as non-impactful in this hands-off as possible and give those patients a huge amount of choice about how and where they communicate with the medical team who will take them through the clinical trial. So is that in the home? Is it in a sub clinic, which is closer to their house than the main investigator site? Is it in a corner pharmacy for their blood draws? So really for that long-term running, giving a lot of patient choice.

So, yes, we're beginning along this journey. We've got some good experience. We're still learning along the way. I think Angela mentioned diversity. And I think that's one of the drivers that we've seen, particularly on the studies that we're now having to -- or want to have FDA

diversity plans in place and really attract all sorts of different people into our study cohorts.

I think giving more choice is really the path forward. So that's definitely an area that we are continuing to explore.

Donato Paolo Mancini Attendee

When you -- just to get this on you on this because it was really interesting, whose idea was it to get the presympto -- to sort of use DCTs for presymptomatic patients? Was it physicians? Was it the patients themselves? Was it you? Who drove that decision?

Jane Twitchen Executive

So all of the above, I mean it was an unusual study for us to really start so early on in the process. And we were very -- we thought that a sort of a flexible protocol with decentralization was the way to go, but we were also very vary that these patients are dealing with a genetic diagnosis they might not be aware of, and there was an ethical responsibility as well. So we wanted to make sure that we got the support right that might not be right for every patient.

Some patients might want to carry on living their life as normal. Others might have a real [thirst] for knowledge. So the flexibility that DCT gives us was really important. And we discussed that with genetic emphasis as well as investigator sites and patients to get the full remitter feedback.

Donato Paolo Mancini Attendee

Fascinating. Stephanie, you're back online, and I'm very happy, but that's the case. The question that we were discussing is what have been your experiences of DCTs, what are the pros that have driven -- what are the benefits that have driven your decision to use them and when you make decisions in this space? So what has your experience been?

Stephanie Manson Brown Attendee

So I'm very hopeful that my connection will maintain. So my apologies to my other members on the panel. I really hope that I'm not causing any disruption and to any of the discussions. I've been -- unfortunately, I did manage to hear Angela and Jane's end input. So some really great examples and also some -- I think just generally, the way that we're approaching things is relatively similar.

We've had a lot of learnings along the way like many people, and we've already been implementing certain end measures with regards to and what we've come under the umbrella term of decentralized clinical trials since before the pandemic, before lockdown, but obviously, that was an impetus for everyone across the industry, really to look at enhancing those options. So just to bring in an example of some of the learnings that we've had is actually about centralizing a lot of our initiatives around decentralized clinical trials. And so Lars and company with multiple studies running in parallel, obviously. This is something that we've made that realization that by bringing a dedicated team in for decentralized clinical trials from an AbbVie perspective has enabled the identification of the commonalities because sometimes [Technical Difficulty] basis or you get clinical study teams addressing it

as per the needs as it pertains to their own clinical trials.

But of course, and that needs to be done when you are thinking about patient care. And obviously, the need as it relates to that particular condition or the compounder asset that you're studying. But there are some commonalities, especially when we're talking about patient reimbursement and end trial support. So just to share some of our learnings, we have 40 trials happening on the therapeutic side. We've got multiple other trials on the aesthetics side of things.

And this is where they really identified some commonalities and identical challenges and that the teams are facing and look to where they could implement certain issues with regards to the management of third-party vendors and making sure that we had a consistent way of reimbursing our patients and ultimately have a more efficient way of solving and some of the problems that crop up rather than everybody having to handle and deal with them and themselves. And so this is certainly confirm a more widespread perspective how we're addressing things.

I head clinical development for aesthetics and aesthetic medicine. And this is an area where we've seen some really great opportunities with respect to enabling more enhanced efficacy measure collection and looking at mobile and image capture, for example, something that previously patients were having to go into and subjects were having to come into sites for regular image capture to enable us to be able to identify and the evolution of the [indiscernible] there, but we've been working on creating tools that enable the patient to be able to capture that at home and putting around -- putting in the robust methodology to be correlate that to existing and full to numerous skills that we use.

Donato Paolo Mancini Attendee

That's fascinating, Stephanie. So are you creating specific software for this, like, for example, apps that patients can put on their phones? Or how does it work?

Stephanie Manson Brown Attendee

Absolutely. So it is software, and it's something that we're looking at applying it to all different types of Androids. And just to kind of get some context, with imaging and regardless of which field you're talking about, the positioning and the lighting of the patients and the distance from the camera, the angle, et cetera, that's a very much plays with regards to the actual image and the results that you're then capturing.

So this is a really important measure to be able to standardize it to ensure that you've got that consistency. And so absolutely, to that point and developing the software to enable back and to see standardization because ultimately, we need to demonstrate to the regulators and we put that robust methodology behind it so that we can provide as an alternative currently. But then ultimately, the future will be looking at and bringing [indiscernible] and some of the endpoints that we're using currently.

Donato Paolo Mancini Attendee

Thank you. Harpreet, what have your experience been like?

Harpreet Gill Attendee

Yes. So not dissimilar to my colleagues on the panel. I think, initially -- obviously, we saw some drive from the pandemic. I think certainly, what we saw at ICON was a little bit of a pull back from going down that -- the decentralized route and there's a level of comfort in going down a familiar route, traditional route. So we saw a little bit of a pullback.

But I think now with the guidance from the FDA and the EMA around diversity and also making trials more available -- easier for patients to participate in from the EMA, I think that's really driving the debate further and pushing us down a decentralized and more sort of broad thinking route as well.

And decentralized, I think, doesn't just mean technology. It's also thinking about some of the other services that could be provided for patients such as community clinics using the pharmacy, home health and using other [sort of concierge] services, et cetera, just to engage them in the trial and ensure they stay up-to-date with the protocol, but also supported through the clinical trial and understand the process as well.

I think education is a really important piece for the patients. We need to do a little -- I think we need to be better at educating patients around exactly what it means to be in a more decentralized clinical trial. I think some -- we did have the feedback that some patients thought it would be more complex, and that's hopefully not going to be the case in most DCTs. So we've seen a range of things. And certainly from our practical experience in terms of delivering some clinical trials for sponsors, we've definitely seen some real benefits around diversity.

I think that is going to be a key part, a key asset of DCTs that you wouldn't see in any traditional trial. And it goes back to the fact that these studies are more accessible. You can generally -- if you're doing things more in your local community, not having to go to a specialized site for all your visits as frequently, that the -- your ability to engage in a clinical trial becomes a lot easier and you get the optionality as well.

So I think we've definitely seen that. We had one study where not only did we see a sort of 50% non-Caucasian population, but we also saw 20% of those come from a rural location. So that speaks to, again, diversity, not just from an ethnicity perspective, but also socioeconomic factors.

Donato Paolo Mancini Attendee

Yes. That's fascinating. As a reminder to our audience, we want your questions and we want them now. I see a couple are coming in, but we want to have a plethora to choose from. So let's move on to the following point.

So I think Jane earlier was saying that there was a -- was there a partnership with Apple? And then Stephanie was talking about their own kind of like software development, let's call them that, to kind of follow up on their patients.

So what are the challenges that you have encountered in terms of technology in operations in conducting DCTs? And are these teething problems that can be addressed easily or are

they significant to the structural issues. Why don't we start with Jane, who can hopefully talk about partnership with Apple as well.

Jane Twitchen Executive

I could do my best to talk a little bit about that. Technology from a kind of mobile infrastructure wasn't as complicated as we expected it to be. I think if you -- I think there's a famous image isn't there of a mobile phone at a concert and sort of 20 years ago, there's three in the crowd and now absolutely everybody has a mobile phone. And along with that comes the infrastructure to deal with that. So looking at Biogen's country footprint, to where we usually take studies and where there's a really strong mobile infrastructure in that particular example, we haven't had huge technology challenges.

Where we've had more, I'd say, challenges or considerations is on what we sort of refer to as the site burden. So what are we going to ask the site to do? How are they going to do it? How are they going to be trained? Do they need access to another portal?

I think sites are really fed up with having lots of different log-ins to lots of different systems and being -- knowing their patients via data rather than patients as individuals, so sort of working through those challenges have been the ones which have been more impactful. Another point, which is maybe moving away from the tech, but it just kind of dovetailed quite nicely with some of the comments we've had about diversity that Harpreet and Angela have also shared. I also wanted to raise kind of the operational piece there because we've got the tech part of DCT, which is absolutely critical, and that's maybe the exciting bit. But then as Harpreet and Angela said, we've also got the -- how do we make it easier for our patients in terms of is someone coming to them? Are they going to a clinic?

Where are they receiving our care?

And we've funnily enough have had more operational challenges with that kind of end of things than we have with the tech. Really simple things, but they're really meaningful to patients. So simple things like if we see a nurse 1 month, we'd like to see the same nurse the next month. If I'm inviting someone into my home, I'd like it to be a face I'm familiar with. Going a step further, I'd like it to be a person that looks like me.

So if I've not got white skin, I'd prefer my nurse not to have white skin.

So trying to -- if an element of diversity is about making this easy for the patient -- making the patient comfortable, I think those parts are really important and maybe vendors aren't necessarily set up to think about all of those parts yet. And then also some sort of logistical challenges that went with that, that often we've got. People coming into their homes and doing blood draws and then the bloods have to be sent off for sampling and that has to happen with dry ice in a courier. So you've got three pieces there coming together. You've got the nurse, you've got the equipment, you've got the courier.

And it's just sort of Stephanie mentioned, having a team of experts who understand that infrastructure, who understand that model, can put that model together for every study without having to invent the wheel from a kind of logistical oversight piece. That's been really critical. So yes, I'd be fibbing if I said there weren't tech teething problems, but I really think

they were more teething problems. And it's the sort of same old operational things that have some level of complexity too that you've got to navigate.

Donato Paolo Mancini Attendee

Thank you so much. Angela.

Angela May Attendee

Yes, I think I would largely agree with Jane, actually. When we've had teething problems, I guess, in specific countries, for example, importing some -- you find out late in the day that there's some weird reason why you can't import this specific device into this specific country. So you have to work around that.

And maybe the vendor or vendors that you're using to provide that equipment or tech don't have specific experience in that country, so then you need to deploy your local team with their knowledge to help you. So we've seen things like that. But I think our tech issues have been more with the build. So actually building the platform or the portal or app or whatever in the first place in the challenges in making sure that it is fit for purpose, that it doesn't land a whole bunch of burden on your sites and your patients, as Jane was saying.

So yes, we might think it's brilliant and it does exactly what we want it to do. But actually, from a site point of view, is it very friendly. So it's been more around that, I suppose, and yes, making sure that, that build is fit for purpose for the study, but also for the users. And in particular, so we've got some experience with hybrid designs and also a fully remote. So this is an interventional study with a fully remote design is the operational pieces, again that Jane mentioned, but you don't have that fallback option.

When you're operating a fully remote study, all of a sudden, your very last resort, which is, well, if it all goes completely wrong, that if we don't want it to be this way, but the patient can go back to the site because they were going to go there, the other visit, where the infrastructure is there.

You have not got that in a fully remote trial at all, and this patient could be hundreds, if not more, kilometers or miles from their nearest centers. So you don't have that fallback option. So it has to work -- whatever that thing you set up has to work. So the coordinating couriers and dry ice and so on. You don't get another option or well, we'll just bring the patient into the site the next day, which we have seen in our hybrid trials quite a lot when things haven't worked out in the earlier days.

But yes, you really need to have these very robust backup plans in those instances.

But yes, I think, as I said, similar to Jane, we've had quite similar experiences really, is just those real nuts and bolts operational pieces that you have to throw away the rule book, get rid of all your assumptions and start again, and there is a way through it. You just have to think differently. And we -- I think we're quite used to not doing the same thing over and over, but it's a very well practice, very well-versed process, setting up your trial, running it, closing it down again. We've done it dozens of times. But all of a sudden, that rule book has completely changed and you have to sort of start being a bit more creative.

So it might not be quite such a familiar area for some people I think. Stephanie has a skill that I've brushed up on recently.

Donato Paolo Mancini Attendee

Stephanie.

Stephanie Manson Brown Attendee

So I'm just listening and noting and some fantastic examples shared there. I think just going back to some of the principles, don't introduce new ways from a technology and operational perspective or process unless a real benefit [Technical Difficulty]. Of course, that's something that needs to be tangible. We need to monitor and adjust as we're going along and ensuring that we're tracking again some of the issues that arrive.

I think one fundamental, that's certainly a big learning point. And I feel like this is probably a very simple observation but make sure that you're writing in and taking all the different considerations and introducing it right at the beginning. So [indiscernible] the protocol, I think that, that's where there's been some challenges, especially when there's been some interest, let's say, some of the optionality that the processor, new technologies provided is trying to retrofit it and go back later in the stage and make protocol amendments. That's not going to make it easier for anyone. So that has been a very simple lesson learned and something certainly that we are taking into account as we're moving forward.

I think also just listening and Jane mentioned around the training, training is imperative. Training is important for the participants, but also the investigators in the sites as well. And this is something that we've actually almost turned into an opportunity. So if you do bring in technology and you're able to actually access and the training for investigators in a much quicker time point, but also in a time that suits their scheduling.

I mean gone are the days where we go for the in-person investigator meetings. We can now do the training in a much more interactive way. And one thing that we brought in for esthetics, for example, and we've talked about diversity, we need to make sure that our investigators are ready to make enhancing patient diversity and our patient population success. And so from an imaging point of view, traditionally through different training or even medical training, a lot of the training that is done on lighter skins. And so we're ensuring that our technology enables training to take into the nuances in the different presentations of conditions but also anatomical presentations as it pertains to different race, ethnicity, age as well and gender, and we need to be looking at diversity across the board.

And then when we do talk about diversity and some of the potential challenges is, of course, it provides an opportunity to break down those barriers and obstacles that pertains to potentially some of the proximity to clinical sites, but we also need to keep in mind we don't want to -- maybe actually further cause issues with regards to divide with accessibility to technology, but also just the comprehension of different tools. And so that then again, is a necessary element [Technical Difficulty] training.

And then just on the same topic, when we're looking at capturing adverse events and we also capture injection site responses on some of our device trials and for injectable assets. We

need to make sure that we are providing that education and accounting for any unintended bias as it pertains to actual self-reporting. Of course, having the real-time monitoring from a safety perspective is a huge opportunity and it enables us to be keeping and turn safety in real time, but we also just need to make sure that the data is consistent from -- with regards to the contexts and how it's been captured and how it's being interpreted. So these are just some examples.

Donato Paolo Mancini Attendee

Do you want to come in Jane, please?

Jane Twitchen Executive

Sorry, Stephanie. She mentioned data and it was a point I meant to raise as a kind of a word of advice that get your data privacy officer involved really, really on. If we're sort of moving through DCT to sort of digital technologies, what is deemed personal data is very fluid. So for example, we've used some devices to measure gait and fall for Parkinson's patients and our data privacy offers are quite rightly, you can say if the right person looks at those, they can identify which patient that is by looking at that patient's data.

So therefore, we need to treat that data in the right way. We need to understand the rules and the regulations for each country. So we've had kind of a few false starts where we've assumed that the data may be -- is not exempt but maybe not the same as patient identifiable information or we use it. We haven't necessarily taken that full breadth of advice as early as we should have done. And the other similar points around data and going back to infrastructures in countries is hosting.

And I guess it's more of a cost warning. It's -- don't underestimate your hosting costs because they can be really impactful to your study budget, particularly depending on geography. So just another kind of early look out to make sure you don't forget about those aspects.

Donato Paolo Mancini Attendee

Harpreet. Sorry, Stephanie. Let's move on with the conversation, and we can come back. Harpreet.

Harpreet Gill Attendee

Okay. Yes. So just quickly, just tech challenges, yes, I think a lot of promise early on with some of the technology that was out there without real thought into what this means for the site and the site burden and also for the patient. So it's really important as my colleagues were saying to ensure that you understand exactly what the nuances of that technology is.

And if you think about digital health technologies, in particular, if you're going to use a watch or a sensor, it's got to be right, not just about picking up the correct endpoint, but is it usable for the patient? You have to think that through all the way. And I was struck by -- I think it was Jane said, it's making those -- looking at the small things in a protocol that can make a difference as to just how applicable the protocol is and how you can adhere to it. It's those little things that really do make a difference.

So we definitely see some sort of technology challenges, I think, a little bit of overpromising and under delivering if I'm sure that resonates with some folks. So I think it's really important just to tease out very carefully some of the risks and challenges. I think the other piece just around operational delivery as well, the sites. We've got to engage the sites really. We've got to support the sites really well.

And again, Jane alluded to it, Angela, that we don't want to overburden the sites as well as we've got to think about the patient, but also sites don't want to be tech support. That's not what they're for. They're there to take care of the patient ultimately and ensure the integrity of the trial at site. So adding all of these factors can be very, very burdensome. So we need to think about the site contract.

Are they being reimbursed appropriately for the work that they're doing? I think there's a line of thought that actually, a site perhaps is doing less work when they're involved in a decentralized clinical trial, and that may not be the case. So we've really got to look very, very clearly and closely what we expect from [Technical Difficulty] for them.

Donato Paolo Mancini Attendee

One thing that I would like to ask you all in is usually people in the pharma industry love to complain about regulators. So what -- how are we doing in terms of the regulatory guidance? Is it going far enough in this field? And where do we need greater clarity? Do you -- what has your experience of dealing with regulators in this space been like?

Harpreet, why don't you start?

Harpreet Gill Attendee

Yes. So I think we all saw that the regulators can move and be very, very flexible during the pandemic. And then we saw them more just again dial back off, which was a real shame because I thought we made some fantastic inroads during that time. We're getting better, a better information now. I think there's some clarity now from the FDA around who's involved at what stage in a DCT and how they should be trained and what the responsibilities are.

I do see there's an awful lot of accountability on the investigator now, particularly coming from the FDA. So I do have some concerns about that additional potential burden. So we'll have to see how that pans out. But I think generally, the guidance around diversity plans, et cetera, is really, really positive. I think it will drive us down the right route.

And again, we're getting some clearer guidance around the applicability of digital hub technologies around computerized systems, et cetera.

So as that develops, I think that will help us take a little bit more risk in terms of pushing the envelope in DCTs.

Donato Paolo Mancini Attendee

Interesting. Thank you. Angela, what about you? Just one thing, I would like us to -- we have about 15 minutes left, and we have -- I'm not joking about 25 questions and some of them are really, really good. So I'm going to ask you to please sort of power through your answers

because there's something else I would like to ask and then I want to move to the Q&A.

But there are really, really some good questions. So thank you, Audience. Angela, please.

Angela May Attendee

I think that the fact that EMA and FDA have both come out with guidance, okay, it's not -- it's still some room for interpretation there, but it's moving in the right direction. So I think they are both very [Technical Difficulty] to the commitment and to progress this in industry. And also a sign that actually they are looking out for us as an industry to try and help us through this journey.

In terms of guidance, I mean, I think more guidance you can get the better in general. I would also say that I think actually when people say lack of guidance, I think we're actually lacking a precedent more than guidance now because there are so few examples. And I'm not -- I'm actually not aware of any firm examples of studies that have used DCT -- significant DCT approaches, full remote or even significantly hybrid that have used this for submission purposes. So of course, around this, lack of precedent is also a lack of clarity and nobody likes lack of clarity. So I think to me, that's where the problem is now shifting from guidance to seeing how this actually pans out in real life.

Donato Paolo Mancini Attendee

Stephanie, what have your experience been like on this?

Stephanie Manson Brown Attendee

Well, I'll keep it relatively top line because I think it's been covered really nicely by Harpreet mentioned already. I mean I think this is where it's partnership, right? And we're all going through this process of being able to, I guess, shape the future, but it has to be set in precedence too, to Angela's point. And I think that this is where we need to keep working forward. There have been significant inroads made, but I think that this is also where -- and to look at it from the perspective of endpoint development, this is where we absolutely need to work in partnership.

Because at the end of the day, a lot of the -- well, the innovation is taking place within industry and partially [indiscernible] within academia as well. And so it's ensuring that all of the difference end steps to be put in place to enable and there to be an acceptance, but also demonstration of the clinical meaningful and significance, but also be able to work at that to demonstrate that it is an alternative to speak to the patient benefits rather than just introducing technology for the sake of it.

So I think that, that is really clear. I mean, this is something that is work in progress. I think there's huge opportunities. Maybe the rate of progress sometimes can feel a little bit challenging. But at the end of the day, we all need to ensure that we are bringing in measures that are the right measures for patients to be able to demonstrate ultimately what the benefit is for them and through bringing in new assets and compounds.

Donato Paolo Mancini Attendee

Thank you so much. Jane, what is your experience in like? Where would you like to see more clarity from regulators?

Jane Twitchen Executive

Well, I guess I was going to echo Stephanie's comment that particularly around the kind of part of decentralized trials, which is related to endpoints or development of new tools for measuring endpoints, we absolutely have to have dialogue with the regulators. The published materials enough just don't give us what we need at the moment. But what we have found is when we've had that engagement with the regulators, they've actually been really happy to have a conversation to give feedback to have several meetings. So I guess, my recommendation is just talk to them. Where you need more, try and talk to them.

It doesn't always work, but so far, so good.

Donato Paolo Mancini Attendee

Thank you so much. I keep getting questions from the audience, and I think I'm not joking, I think we're about 25 in. So what I'm going to do is I'm going to combine. I'm going to do a medley of questions, combine one from the audience, and I combine them with the talking points that you're familiar with. And here it is.

Donato Paolo Mancini Attendee

So how do the economics of running a DCT stack up against a traditional CT? What are the expectations in terms of accelerating the CT process as a whole by decentralizing the process, which kind of blends in with what are the factors behind the positive impact, the positive fiscal impact of DCTs? What are the benefits beyond cost savings? And where are the returns most compelling? And how can we measure these improved financial outcomes in DCTs?

Harpreet, why don't you start answering?

Harpreet Gill Attendee

Yes. I'll be really concise. So a couple of headlines here. So comparing a DCT to traditional, we're going to see -- our experience states you're not going to see a big difference in terms of baseline cost for delivering that study. However, where you will see a difference, we believe, is in terms of the outcome.

So the outcomes, if those improve in terms of patient retention, you're going to save some money there in the long term.

Adherence to protocol, you're going to save something there in the long term. And then there was a third point, it's gone straight out of my head. But generally, just looking at the overall outcomes of the study rather than what's the baseline cost of the study, that's what we need to look at. What are the improved outcomes because that way you can see in the long term, there's an improvement. We know about protocol amendments.

If you don't get it right upfront, that there are sort of issues around, as I said, retention, engagement, et cetera, of patients and adherence to protocol.

If you can improve that during the trial by using DCT methods and we have seen improvements in diversity and retention, certainly ICON, then you will impact the outcome. So I would say focus on the outcome rather than the baseline budget at the beginning.

Donato Paolo Mancini Attendee

Jane, what is -- what are your thoughts on the economics of DCTs?

Jane Twitchen Executive

Yes. I think Harpreet has absolutely hit the nail on the head. Our experience is incredibly similar. Advantages of [RIM] recruitment and retention, not in operational spend or the cost of doing the trial. I think the only other piece I'd add in is, and this is more about the digital health endpoint development.

Is there potential to basically minimize the white space in your clinical development plan because you're thinking about what are my future endpoints going to be when you're earlier in your portfolio. So actually bringing your product to market a little bit earlier. We've got some opportunities that we haven't had before, but cost per study, I think Harpreet hit all the key points.

Donato Paolo Mancini Attendee

Stephanie, what are your thoughts on economics of DCTs? Where do you see the biggest kind of benefits?

Stephanie Manson Brown Attendee

Well, I would say just before I go to benefit, I think it can be maybe challenge if you are just looking at metrics from an economic and a cost decrease because then we're going to lose out on opportunities to introduce into the clinical trials. And so therefore, I think if we are so reductive on that element, we will never make progress. But exactly, it is building all the other metrics and KPIs.

I think there are some cost savings that can be done, and we were looking at this from an imaging perspective. So I mentioned earlier by bringing in these end mobile-based, end imaging solutions. And that's something that definitely when we look at it from the shorter and then to the longer term, will definitely provide cost savings. And this is something that will be very important for us then to look at how we recoup and the costs that were associated with developing the technology in the first place. And so therefore, it's always a trade-off and we're looking at evaluating the balance there.

But I think that this is where by providing when we're looking at it and the -- and at home or the mobile device solutions, this will then enable us to continue to look at cost savings there, but then to continue to invest in and how we can further develop the technology. So there are cost opportunities, but it's not certainly not so focused.

Donato Paolo Mancini Attendee

Angela?

Angela May Attendee

Yes. I mean it's difficult to follow now because everybody made the main points. But actually, I've got quite a good example of which sort of highlights a lot of the things that everyone has been saying. So definitely, it's focusing on the outcomes, not the top line going into your study budget.

But we've got a pediatric study where we deploying, again, optional, but DCT options for these patients to really reduce that patient, but also caregiver burden. And we're looking -- focusing on the younger cohorts because obviously, [indiscernible], you start with the older age groups and move down to the younger ones. Well, you look at the parents with a sick child and probably traveling across the country to get to a specialist center to treat their child's disease and offering up these alternatives, which means they don't have to do that. That journey is going to be quite -- should be very well received.

So we've had a lot of input from our KOLs and patient organizations to say, look, this is what we want. Do we do want this option? And in this specific example, because pediatric studies are often part of your -- the bigger picture of pediatric development with your product's life cycle. If we can recruit an additional x number of patients, and these are small numbers, but if you can attract these patients that the caregivers just wouldn't have consented, this could translate into quite big numbers.

And we've sort of modeled a few scenarios and so on and feel that we can make months of difference to the closure of this particular study, which obviously from a life cycle point of view is considerable. So it's a very specific example. But I think if you really can make that difference and it just highlights Harpreet's point, if you can really make that difference to when your trial finishes, there's a huge financial gain that could be made there. And more importantly, that drug gets made available to people that need it earlier.

Donato Paolo Mancini Attendee

Let's combine another two questions. I mean there are seriously some really, really good questions from the audience. So do you -- and very, very briefly, lightning round. So do you engage with patients or patient organizations? I want to use that as a springboard, Angela, what you just mentioned.

Do you engage with patients or patient organizations-designed trial protocol, software education tools? And what has been the impact of DCTs on getting clinical medicines or supplies to the patients? Angela.

Angela May Attendee

Sorry, I missed. You cut out -- the last part of that question, sorry. I can't hear you. Is it just me? I can't hear Donato.

Jane Twitchen Executive

We neither. Donato, you're cutting out. Maybe between us, we could start with a question about insights from patients, Angela?

Angela May Attendee

So yes, well, I think we talk -- we did talk about it a little bit before, didn't we? And I know he was pulling on a point I'd made about this pediatric study. But I think you -- absolutely, and we talked about it earlier when we talked about end users, didn't we? But you need to engage your patient efficacy groups and whatever.

You need to understand the challenges for those people and what it means to them and what it is they're looking for because what you might assume, even as a no-brainer, you might assume we should definitely do this way, could be completely the opposite when it actually comes down to it. So I think it's absolutely critical to engage these sorts of organizations.

Harpreet Gill Attendee

Yes. And if I might add just in terms of -- obviously, at ICON, we also talk to patients as well, patient efficacy groups and then during the running of the DCT. We can also send out surveys see how the patient is feeling about being involved in the study. But I would say that one thing that we've heard time and again around the protocol, and this isn't just about DCTs, frankly. It's more broadly from a patient perspective is that so often protocols are all about the scientific endpoint.

What the -- maybe what the clinicians think might be useful or the scientists might think is useful. But actually, it's not going to make much of a difference in the quality of life of me as a patient. So why do I care?

So we've really got to listen to the patients. What's going to make a difference for them when we develop the protocol. And then you can put -- think about DCTs as well. What is it about engaging in the clinical trial, what will make it easier, what will make it beneficial for them? So it goes from the protocol, the protocol design, what's in it for me as a patient, but also making it easy for me to engage.

Donato Paolo Mancini Attendee

I hope you can hear me now. Can you hear me now?

Jane Twitchen Executive

We can.

Donato Paolo Mancini Attendee

Stephanie, would you like to come in.

Stephanie Manson Brown Attendee

Yes, of course, the patient voice is vital, and we do connect with the patient groups to better understand how we can be designing all of the different elements from protocol design and bringing new technologies. I would say a couple of things, and there's research to show that end patients and subjects are open to technology and open to the different [Technical Difficulty] and whether that's the new digital wearables or technology being brought in as long as there's an education around there.

Then we also need to kind of keep in mind that they do like in the main state to have that interaction with their doctors. And so therefore, we do need to enable that dialogue is maintained throughout the end clinical trial because that will obviously and help with retention as well. And I think also then the diversity piece, we want to be inclusive. So when we're speaking to patients, we need to keep that in mind. So one patient does not represent all of the patients within a certain condition.

And so that is really important to ensure that we're taking in all the different perspectives and bringing that into what we do. And then obviously, there is an option then to take those considerations into whether it's endpoint [Technical Difficulty] or even just the accessibility to the tools, for example, and of course, the education piece around it.

But I think that there are often -- the benefits are understood by subjects in the trial, but obviously, there's just about the maintenance of having that end access. And there's definitely opportunities in the future as well for subjects and trials and patients then to be able to have time access to some of their data metrics.

Donato Paolo Mancini Attendee

We're running out of time.

Stephanie Manson Brown Attendee

Sorry, I'm just -- it's a topic that I love, but anyway [indiscernible].

Donato Paolo Mancini Attendee

Very briefly, Jane, super briefly.

Jane Twitchen Executive

Super briefly. Along the lines of everybody else, absolutely patient insights are really key. And also investigator insights or protocol simulations from both the investigator and the patient perspective can be really useful. And the other point I was going to make really quickly is don't second guess what the patient wants. We think someone coming into your home is easiest.

Actually, it's an invasion of my privacy, I'd rather go out. So just ask the patient. Yes, I think, it's my learning there.

Donato Paolo Mancini Attendee

Thank you so much. I want a one-word answer from each and every one of you. In what phase -- what clinical phase do decentralized clinical trials make most sense? Jane, one word, one number.

Jane Twitchen Executive

2.

Donato Paolo Mancini Attendee

Okay. Stephanie?

Stephanie Manson Brown Attendee

I say 2, but I also work on device so feasibility as well.

Donato Paolo Mancini Attendee

Angela?

Angela May Attendee

In our experience, 3.

Donato Paolo Mancini Attendee

Harpreet?

Harpreet Gill Attendee

2 and 4. So all of them.

Donato Paolo Mancini Attendee

I'll hand over to Harpreet for her closing remarks and then we need to wrap up.

Harpreet Gill Attendee

Yes. So I just want to thank my panel. It's been a fantastic discussion, really insightful, really interesting. Some amazing insights that have been shared. And I think we've all learned from each other and hopefully, our audience here as well.

I just want to thank Donato for moderating as well. So thank you very much, and I'll hand back to you to wrap.

Donato Paolo Mancini Attendee

Thank you. Look, it's been a wonderful super-engaging panel. We're running out of time. Despite the technical difficulties, we made it through, some really wonderful insights. Thank you for being with us.

This video will be available for another 30 days. And for today, that's it. Thank you very much, and goodbye from the FT.

Jane Twitchen Executive

Thank you.