Do we have the right understanding of how patients perceive digital clinical trials?

Interview with Trishna Bharadia,
Health Advocate & Patient Engagement Advisor
on the 1,133 patients survey results conducted by Kayentis in 2020

Kayentis

As the COVID19 pandemic significantly impacted clinical trial continuity and catalysed their digitalization, we conducted a study to explore patients' readiness for remote clinical trials.

- An 11-question study investigating the experiences of and expectations from clinical trials of people living with multiple chronic conditions.
- Study conducted between November 2020 and January 2021.
- 1,133 people living with health conditions, including from several patients' associations, across North America and Europe, volunteered their time to respond anonymously to this survey.

In this white paper, Estelle Haenel, Kayentis Medical Director and Basile Trimbur, Kayentis Medical Assistant, interview Trishna Bharadia to get her feedback regarding the results of the study.

Interview with Trishna Bharadia,

Health Advocate & Patient Engagement Advisor

Trishna is an expert in bringing the patient voice into the healthcare journey. As a health advocate and an industry advisor, she works with multiple stakeholders including pharma organisations, patient associations, individual patients, and clinicians. Present internationally, she addresses issues that affect patient communities as well as the health care industry. She is extremely well connected, and her network is instrumental when it comes to establishing collaborations with patient groups, which has been paramount in our study that is talked about in this interview.

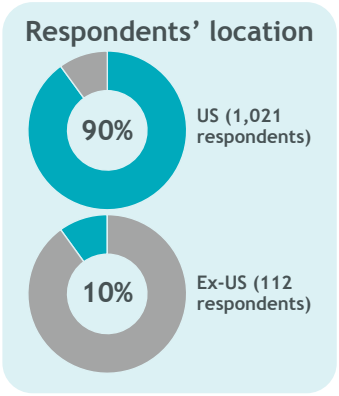
Given her deep knowledge of how patient communities work and her huge expertise in what pertains to patient engagement, we asked her not only to help us build the survey together but also interpret its results.

“Having a patient advocate involved in any patient survey is important because it’s embedding patient centeredness more deeply into the project itself. It’s not just about going to get some insights from a group of patients, it’s about making sure that the way in which those insights are gathered is relevant. I was involved in co-producing the survey, which included making sure that the duration, the format, the tone, the use of the language was all patient-friendly. I supported the dissemination of the survey, which means that when it went out, it went out through my own wide networks. I know that I helped to introduce Kayentis to patient groups so that those longer-lasting relationships could also be formed. And then, contextualization of the results and the interpretation is really important because unless you give context to those results, they don’t mean as much and you know we will also be helping to make sure that the results are disseminated to as many people as possible.”

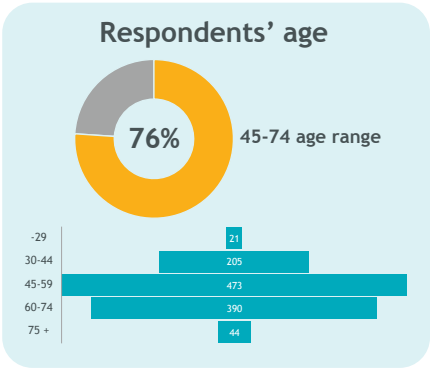
Survey Participants

What do you think about the Demographic data of the survey and the patients' conditions?

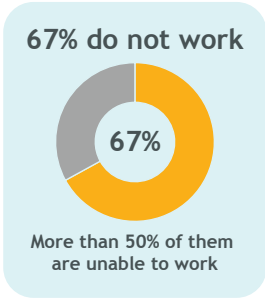
Firstly, we had a great response! Well over 1,000 people participated and the vast majority of respondents (in fact 90%) were from the US but that's not actually surprising given that one of the patient organisations that helped us to disseminate the survey is US-based and its members are part of a patient community that is well known for being quite engaged and activated.



"There was actually a large response from the 60 to 74 years of age category. There were 390 people in that group, and I found that surprising because this was an online survey. It just goes to show that we can't assume that older people aren't engaged online."



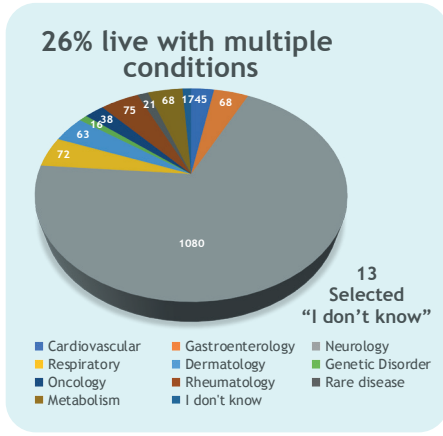
In terms of age, the biggest response was from people between the ages of 30 and 74. Again, not necessarily surprising when you think that our dissemination channels were largely going to attract people who are living with long-term conditions.



“67% said that they weren’t working, and over half of those who cited the reason for them not working was that they were unable to work. This has some important implications when it comes to clinical trial participation.”

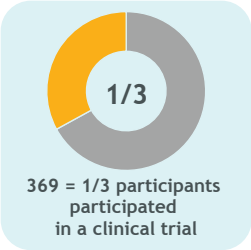
And then, finally, we had a good range of conditions that were represented, although we did notice a large proportion of people coming from the neurology area. But this is to be expected because we disseminated the survey through the Multiple Sclerosis Association of America and also Parkinson’s UK. But amongst the non-neurological conditions, there was a really good spread.

“26% of people also said that they lived with multiple conditions. Now, again, this is really important to take into account if you’re designing a trial because inclusion and exclusion criteria can often prevent someone from participating if they live with other conditions.”



Participating in Clinical Trials

1/3 of the survey respondents already participated in a clinical trial. Do you find this number surprising?



I actually thought this was a really good figure and it wasn't surprising given that our dissemination methods meant we were more likely to be getting respondents who are living with conditions in which clinical trials are common. And also, there may have been a weighting towards our respondents being more informed than the general population, so they're more likely to find out about clinical trials or be informed enough to understand the value of participating.

I like to talk about there being different types of patients:

- The patient by experience: this is the vast majority of people who are diagnosed with a condition, and they're just living their lives day-to-day with enough information to get by (or maybe no information!), and they might just be relying on what their doctors tell them.
- The expert patient: these are people who are informed, they're engaged, and they're generally active in their healthcare decision making.
- The pro patient: what I call the pro patients are patients who are not only experts in their own condition, but they are also aware of the issues that are affecting all patient communities.

“Now, this is important to understand because the awareness and experience of a clinical trial can be impacted by the type of patient and how engaged they are.”

So, I think that this can have an impact on the responses to the questions that we were asking.

What is essentially keeping patients from joining clinical trials?

Something that came out really clearly in this survey is that trial awareness is a glaring issue. Among those who hadn’t participated in a trial, 70% said that it was because they were unaware of them.

That’s a huge percentage, but also, in a way offers some hope because it’s a relatively low hanging fruit, so to speak. In terms of being able to address this challenge, it comes down to ensuring that promotion of trials and recruitment is targeted, is relevant, and is via the appropriate channels.

“To do this, we need there to be better relationships with patient organisations, with patient advocates, with sites, with healthcare professionals, and with some of the less traditional organisations such as community organisations, because we need them to help to educate people about the importance of clinical trials, and also, where they can find out more information.”

For me, not knowing about a trial is a really poor reason as to why people are not taking part, and I was actually shocked by such a high percentage. I don't think it's surprising that 17% of people said they were unable to participate for practical reasons, so things like distance to the site, expense, because we often hear about what we call the "burden" of clinical trial participation.

> ***"But what's interesting here is that survey respondents who aren't in work are more sensitive to some of these practical considerations, with just 8% of those working saying that help with costs would make their clinical trial experience better but 15% of those who don't work saying the same thing."***

A similar trend was seen for perspectives on travel distances to the site as well.

And then finally, I think it's important to note that of the 6% of people who said that they had been asked to participate in a clinical trial, but who said no, 55% said it was for health-related reasons. So, for example, possible side effects from the study drug or the possibility of receiving a placebo, and this is really where management of expectations would really come in.

Those who refused to join a clinical trial

Possible side effects from the study drug	29%
The possibility of receiving the placebo or fear that your disease would not improve	26%
Fear of burden generated by study procedures	14%
Lack of information on clinical trials	8%
Length of time of the study	8%
Cultural or personal reasons	6%
Hospitalization	6%
Uncomfortable with mode of data collection	2%

55%
Patients refused to join a clinical trial for health-related reasons

What do you think the industry should or could do to solve this problem of patient participation?

Taking note of surveys like this one is a really good start!

> *"I think it just shows that we can't assume that we know why patients aren't participating in trials."*

I've already mentioned that we need better collaboration between all stakeholders to ensure that trials are relevant.

We need to make sure that they're appropriate. We need to make sure that they're properly advertised so that people who should know about them, do. You know, a lot of this comes down to good patient engagement strategies and really breaking away from some of the more traditional ways of thinking. It is well known that recruitment and retention are two key obstacles for successful clinical trials.

So, industry needs to stop doing what it has always done and look at things differently.

This starts right from setting research priorities, but I'll emphasize again what you know based on this survey's results.

> *"The one major thing that industry can be doing is improving the awareness of clinical trials in the first place."*

Patients in the 30-59 age groups are the ones showing the strongest fear to participate for health-related reasons as compared to other age groups in our study. How do you interpret that?

So, from my own personal experience, I actually fall into that age bracket and knowing the experiences of others within patient communities, I'd say:

> ***"It's because at that age most people have commitments that can make you more scared of a clinical trial not working."***

They could be working, they might have young children or elderly parents to look after. They might have financial commitments and personal commitments. All of this might make them more fearful of the unknowns in a clinical trial, particularly if there are alternative options available that have been tried and tested and we know about. I think there might be an element of younger people generally being more risk-takers and also older people thinking "well I have nothing to lose" but in that middle category I think this is quite understandable that there might be a greater fear of participating in clinical trials.

> ***"I think having clear and simple information, particularly around informed consent and patient participation sheets can maybe help alleviate some of these fears."***

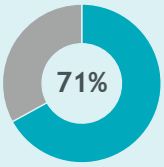
Simple and clear information was something that did come up as being important to people within the survey, and I think it can alleviate some of the fears of the unknown if you kind of know what you're getting yourself into and also what the possible risks and benefits might be.

Experience with digital solutions and clinical trials decentralization

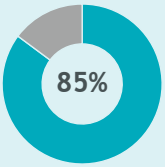
71% of patients who already participated in a clinical trial used electronic devices, and more than 85% of them rated their experience with digital tools highly. Do those figures come as a surprise to you?

Both figures came as a surprise, but a nice surprise.

We often tend to believe that uptake of digital solutions is still very low, and there's still reluctance to embrace technologies both on the side of the site and also the patients. But this just goes to show that, actually, that might not be the case.



71%
respondents who participated in a clinical trial had experience using an electronic device to complete study questionnaires



85%
rate well their electronic device use experience **(selected 4 & 5 on a 1 through 5 scale)**

It's also interesting that neither age nor therapeutic area had an impact on this. I think this puts the industry in a good position to further embed the use of digital tools into clinical trials, knowing that there's already a base for potential success there.

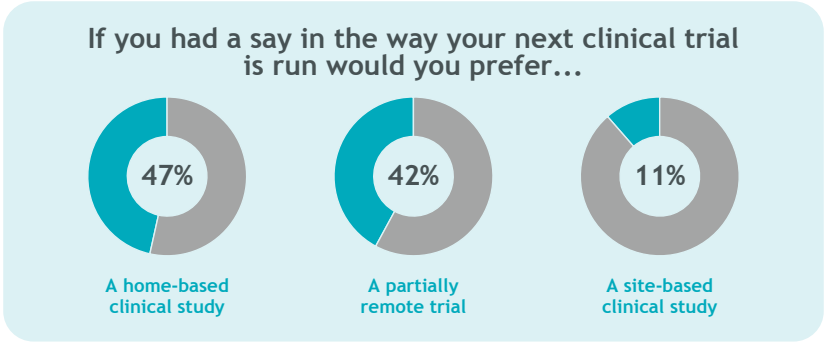
Prior clinical trial participation has an impact on the perception of the patients on what matters most from using digital tools in clinical trials. How do you understand this?

I think this comes down to actually having the experience about what a clinical trial involves, and how digital tools can be used to improve this experience. If you've never taken part in a clinical trial, then you're basically guessing about what you think might be useful. This is very clear, actually.

> ***"From the fact that just 13% of those who hadn't participated in a clinical trial said that digital tools were important for them to be able to speak with the study doctor or nurse via video calls. But 27% of people who participated in the clinical trial said the same thing."***

There was also a 10% gap when it came to the importance of training on the device. I think this shows that people who participated in a clinical trial were, perhaps unsurprisingly, aware of different things around digital tool usage within this particular setting.

89% of patients said that they are ready for decentralized or hybrid clinical trials. Were you expecting such a high rate of patient readiness for this type of clinical trial operationalization?



I actually think this is a really interesting question, because if we had been discussing this pre-COVID then it would have been surprising. But there is a lot of research out there now to show that COVID has had a profound impact on patients' willingness to go into a hospital and/or site setting. COVID has accelerated the use of telemedicine and digital health tools (and also just digital tools in general). How many of us have had Zoom calls with family and friends, for instance? It's become something that patients are much more aware of.

> *"COVID has really helped in terms of embracing the idea of decentralized trials in a way that maybe might not have happened so quickly or so deeply outside of that pandemic situation."*

“I think that totally or partially remote trial preference will last.. It’s not about having one thing or another. I think it’s about increasing patients’ choice because even outside of COVID, decentralized trials actually would have suited a lot of people, myself included.”

I live a great distance from most clinical trial sites, so being able to have something which is decentralized, being able to do some of the testing and monitoring remotely, would actually increase access for somebody like me. And that doesn’t change whether or not we’re in a pandemic.

“It’s going to be about providing options and then - in that way - increasing access to clinical trials for a greater variety of different patients.”

Any last recommendation you would make?

There are some key things that have come out of this survey that sponsors, sites, solution providers and so many other stakeholders in the clinical trial ecosystem can take on board.

Firstly, informed patients would likely join clinical trials. The vast majority of patients are ready for hybrid and decentralized trials, so we need to make sure that continues moving forward. There is a strong need for clear, targeted, and focused information. And we shouldn't subscribe to traditional assumptions—like age for instance—affecting expectations and perceptions of digital solutions or what people want, things like gamification.

This survey has shown that what people want most is the ability to conduct remote visits, have a user-friendly device that offers them things like reminders of their trial obligations, and also to be able to chat with site staff or support staff.

Finally, underpinning all of this, in my opinion, is good patient involvement in the design of clinical trials and clinical trial solutions.

Study conducted by:

Estelle Haenel
Kayentis Medical Director

Basile Trimbur
Kayentis Medical Assistant

Testimonial from:

Trishna Bharadia
Health Advocate &
Patient Engagement Advisor

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