WORKSHOP REPORT: Reuters Pharma Japan 2022

Taking clinical trials to the patient

Putting patients at the center of trials in Japan using new tools and approaches

The pandemic was a catalyst for change and had an enormous impact on the clinical research industry. Emergency measures introduced after the outbreak to keep clinical trials running around the world are now transforming future trials for patients in Japan.

The extensive adoption of digital and remote solutions during the pandemic provided a new roadmap of what is possible for clinical development.

Trial teams are well equipped to gather key data in the home, either through telemedicine, physical visits from nurses or via wearables. Direct-to-patient shipping capabilities also reduce patient burden by removing the need for on-site clinical visits for re-supply.

The benefits of these approaches are already evident. In a survey of over 800 participants enrolled in clinical trials during COVID-19, 35% of respondents reported spending less time going to research visits at sites or hospitals versus before the pandemic.

Putting patients first

Clinical trial participants clearly like the convenience of these new capabilities and have voiced their opinions on the downsides of centralized trials. Those tasked with creating and running trials are listening.

"Based on direct feedback, clinical trial participants have expressed how inconvenient it is to be stuck for so long in hospitals or medical facilities, and the burden of frequent tests," says Shigeki Tanaka, Executive Vice President, Head of Japan-Asia Development, Astellas. "These insights are informing the planning of future clinical study protocols. It is exciting to see this happening so that we can better meet patient needs."

Tanaka's observation is backed up by a CISCRP 2019 survey conducted before the pandemic that found that up to 80% of clinical trial participants and potential participants found collecting all data at home, having home health visits for all study visits, and a hybrid approach of at home and in-clinic visits to be appealing compared with all in-clinic visits.

Now, with the benefit of all these learnings pre and post COVID, it is no longer business as usual. It is clear that a greater degree of decentralization is the way forward.

Risk taking versus risk hedging

Despite the increased awareness of patient preferences and the potential to expand remote elements in trials, progress to date remains limited in Japan. Moving to a more patient-centric approach faces a series of challenges.

DCTs have not been widely adopted in Japan for several reasons, says Dr Hirotaka Nagashima, Director, Clinical Research Hospital, Tokyo. "The strongest reason is the difference between digital and pharmaceutical cultures, as well as differences between foreign and Japanese cultures. Foreign cultures tend to be more risk-taking, while Japan is a culture of risk-hedging. This causes us to hold back on moving forward until there is zero risk."

This needs to change, says Nagashima, or Japan will be left out of the global innovations in DCTs. "We can't just keep giving reasons for why we can't [do this]."

Vested interests are one reason DCTs are not yet being widely adopted, says Takeshi Mori, Senior Director, Project Leadership at Parexel. "It's easy to imagine a future where DCT implementation eases the burden for medical institutions."

"When that happens, those with vested interests could possibly lose their jobs, or it could be that they're avoiding the hassle of implementing new processes. I think this pattern of thought may affect CROs as well. When a DCT moves forward, CRO business may change significantly."

"There is certainly a defensive stance in some clinical institutions. While working with several CRCs from medical institutions, I've heard some of them express a fear that their relevance will be eroded in a DCT future," says Toshiharu Sano, Associate Vice President, Japan Development Head of Clinical Operations Area, MSD.

They may also not be fully aware of how DCTs benefit patients "I believe that's another area we need to address to get them on board," adds Sano.

Building out DCTs

While there are challenges, there is nonetheless a groundswell of support for DCTs in the healthcare and pharma sectors.

The solutions to the practical elements of conducting trials remotely are already being solved, says Nagashima, and it's possible to imagine a better future for all stakeholders. "Our clinic in Nihonbashi is quite large with30 staff members and we anticipate we would see many difficulties if we attempted to switch to DCTs immediatelyI but if we made the decision to focus on DCTs, our location could be much smaller and require fewer staff.

"Business operations would become easier, and costs would also likely go down. Even if the transition is difficult, specializing in DCTs could simplify clinical trials."

The virtual clinics conducting DCTs in the future will have three elements, says Nagashima. "First, a virtual PI, and a CRC or coordinator who can work virtually. There's no need for me to build a big clinic and sit there all the time. As long as you have a computer, you can be a virtual PI."

This still necessitates local nurses and CRCs, however, entering someone's home so protecting their privacy is an important consideration. "A possible solution is doing such work in the car."

The way forward

How can trial stakeholders make change happen?

The JPMA's DCT taskforce has already outlined a strategy says Masayo Miyata, Director, Trial Lead Department, R&D Div, Janssen Pharmaceutical K.K, Japan. The tools it has developed could be implemented by everyone immediately, especially given the permissive regulatory attitude during COVID.

"Which begs the question why they're not being widely used. Our company has also used tools such as e-Consent, and the issues tend to be that the merits are not clear, and medical facilities aren't taking the initiative in utilizing these tools. This is something we need to help senior members better understand in order to implement these changes."

The creation of a specialized institution would also help, says Nagashima. "The cost savings are immense, and business operation becomes so much easier." All the approaches outlined in the JPMA information can be realized"and when implementing these methods in doctor-led clinical trials, they work. It may seem idealistic, but I believe by working together we can create a strong system."

There are reasons to be optimistic about DCTs. It is important to recognize that there is broad agreement that the concept of patient-centric DCTs is the future and change will happen, says Nagashima. "It may be difficult at the start, but if it is a good thing, and there is a demand for it, change will happen and that momentum will carry us forward to success."

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