A workable, humanized approach to patient-centric decentralized clinical trials in Japan

The patient's voice matters even more as the pandemic draws to a close

As 2022 ends, the industry is consolidating what it has learned so far about implementing decentralized clinical trials (DCTs).

The pandemic provided a unique opportunity to advance the DCT model, which was in its infancy as infections began to rise. Finally, almost three years later, the industry has workable solutions, and patients have a say in what works for them.

It seems ages since 2017 when Dr. Hirotaka Nagashima, Director of Tokyo Center Clinic, envisioned a new model that enabled home-bound patients to participate in clinical trials through online consultations.

Over enough time, however, the system evolved to include more than an online dialogue during the pandemic. Now, a fully mobile clinic of nurses and technical staff can be dispatched to patients' homes. Digital devices to fill the gaps in care will be the next step but this is not the only consideration, says Dr. Nagashima. "It's not just technology that's being used. The other is reform in the way medical personnel work."

According to Dr. Nagashima, the physicians providing online medical care were primarily female physicians who were on parental leave or otherwise wishing to work from home. And years later, the pandemic forced greater numbers to work from home. Now he says, "I think this may be a new type of work style for [all] doctors and medical professionals as well."

Working patterns have been slow to change, says Mr. Toshiharu Sano, Associate Vice President, Japan Development and Head of Clinical Operations, MSD K.K. "Benefits to the hospital and workstyle reform have not been considered."

This needs to change, Dr. Nagashima comments, “I dare to encourage my medical staff to work from home, and I do it myself. I think the pandemic has made telecommuting the norm for pharmaceutical company staff and some CRO and SMO staff too. So, I’ve always wanted to reform the way people in healthcare work.”

A hybrid approach

For DCT methods to become more widespread, medical institutions will need to specialize in DCT functions, but also introduce a hybrid approach that combines face-to-face and online treatments, predicts Mr. Tomohiko Takahashi, Associate Manager, Otsuka Pharmaceutical Co., Ltd.

In contrast, Dr. Nagashima states that introducing a hybrid practice is a challenge for medical institutions. Currently, medical institutions can focus on either face-to-face or online, but not at the same time. Therefore, much will need to be done to implement a hybrid solution. For example, separate organizational structures and staff training are needed for onsite and online medical services.

What must not get lost in the process of innovating clinical trials is the personal touch. Staff should remember the importance of helping patients feel reassured and supported. “Most importantly, it’s not just about technological advances, but about a return to a warm, patient-centered, true medical practice,” adds Dr. Nagashima.

Medical institutions will also need to focus on the reliability of data collection methods because “The key to making all this happen is understanding how to use real-world data as evidence and whether we can accept the data.”

A decentralized, Covid phase-3 trial

Lessons have been learned from a phase 3 clinical trial for an oral drug to treat Covid-19 during a fifth wave of the infection. Seriously ill patients were either hospitalized or treated in Covid-designated hotels staffed with medical personnel. Recruiting participants from these locations was possible.

However, one of the biggest challenges was to figure out how to reach mildly ill patients at home, enroll them in the study, and provide home visits and online examinations, says Ryohei Tanigawa, Clinical Development Manager, Kyowa Pharmaceutical Co., Ltd.

He says that without a DCT and the involvement of Tokyo Center Clinic, including patients with mild disease would have been impossible.

We must not forget how remarkable it is to carry out the DCT in these difficult times and implement it speedily, says Shigehiro Miki, Representative Director, General Manager - Japan, Parexel International. “I think it’s wonderful that you are taking on challenges in areas where no one has gone before.”

Unfortunately, the primary objective of the trial was not achieved, however, implementing the DCT enabled early enrollment and half of the target number of 1,000 could be enrolled. In addition, patients infected with Covid were presented with various anxiety provoking situations and regular online meeting with trial staff seemed to help them feel more secure. Therefore, Mr. Tanigawa believes he can apply the lessons learned here to other treatment areas.

The regulator has an important role to play in helping build on the innovations in DCTs from here, since DCTs cannot be implemented unless the regulatory authority in Japan, the Pharmaceuticals and Medical Device Agency (PMDA), approves the protocol.

The methods of gathering data need to satisfy the regulator, Mr. Tanigawa says. “The PMDA is concerned about obtaining the same level of data from hospitals, hotels, and homes. Therefore, they will ask you to ensure consistency in how you collect data and interpret the results.”

The patient’s voice and insights matter

Incorporating patient insights into clinical development is another lesson learned for Tatsuyoshi Yamamoto, Clinical Operations Director in Japan, JCR Pharmaceuticals Co., Ltd. “The patient’s voice is indispensable for projects that are difficult to develop, such as those for [orphan drugs treating] rare diseases,” he says.

JCR Pharma has developed a treatment for Hunter's disease. The company received "Sakigake" designation (early commercialization of innovative drugs) in Japan and orphan drug designation overseas for the drug.

The phase 3 study in Japan collected qualitative data in interviews with patients’ families and used to evaluate efficacy of the treatment. Data collection in the form of interviews is unprecedented in Japan, and although there were some cases where it was difficult to conduct the study because the institution did not agree to conduct it, or the consent of the patient's family could not be obtained, useful data were obtained from several patients.

In discussions with the PMDA at the start of the clinical trial, Mr. Yamamoto says that they were able to agree on a difficult trial design by incorporating the opinions of patient and family association members.

He says, “The patient’s opinion alone would not be sufficient to convince the PMDA. I think the overall consensus was reached based on the data’s scientific validity and medical expert opinion.”

Even though he’s been met with some resistance, Mr. Yamamoto says he would like to continue receiving evaluations from patients or their guardians. “The [real] story, as Mr. Tanigawa and Dr. Nagashima mentioned, is about how to pick up the earnest and sincere voices of patients and realize them.”

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