WORKSHOP REPORT:

# Implementing patient-centric decentralized clinical trials in Japan

By Reuters Events: Pharma Japan 2023

## Implementing patient-centric decentralized clinical trials in Japan

*Now into the third year of the Covid-19 pandemic, a virtual and patient-centered homecare services solution for clinical trials is here to stay.*

The new model that has emerged in response to the pandemic in which a virtual control center orchestrates online medical examinations and dispatches vans to patients' homes has created the opportunity to expand virtual and homecare services in decentralized clinical trials (DCT) centering on the patient, says Dr. Hirotaka Nagashima, Director of Tokyo Center Clinic.

It is an approach involving the close integration of people, IT devices, and mobile solutions that was developed from the early days of the outbreak of Covid in Japan.

### Natural evolution to a patient-centered clinical trial

During the outbreak of the pandemic, medical personnel were exposed to the risk of being in close contact and infection. Under these circumstances, physicians began providing online medical care and nurses were assigned to convalescent hotels. At the time, "there was a lot of talk about how to use [online tools to reach clinical trial patients] and not much else," says Dr. Nagashima. The online medical examinations were only part of the solution, and the entire process required a broader deployment of services, he says.

Thus, the Tokyo Center Clinic acted by expanding home-visit nursing care besides providing online medical examinations. Altogether, the team can be considered to comprise a virtual clinic and an online examination room. Says Dr. Nagashima, it's a virtual clinic where everyone can participate, and that is what we call the 'orchestration of people' including project leaders, home-visit nurses, and patients.

During a virtual visit, on one Zoom screen it is typical to find a project leader, home-visit nurse, and others. Patients log in on iPads for virtual examinations and use their cell phones to log daily temperature, oxygen saturation level, and blood pressure, among other data in an application. People are the virtual clinic. Technology tools support them.

This model, developed in the throes of the pandemic, now has the potential to be the way clinical trials will be conducted, whether we are in pandemic or not.

Dr. Nagashima believes the role of the project leader will be the driving force of the DCT, the concert master, so to speak, and compares the workings of the DCT to Seiji Ozawa conducting his orchestra that requires the players as well as their instruments to perform.

## Bringing a DCT directly to patients

Patients who would have never participated in a clinical trial can do so now because nursing staff are ready to visit, traveling in a fully equipped van to meet the patient at their homes and physicians are ready to meet patients virtually through the online conferencing software. The customized van is equipped with computer, iPad, refrigerator, testing, and sample preparations equipment. Samples can be collected, and any direct testing can be done in the van. In a typical day, a van can visit three or four patients. The target is to have the DCT cover up to 80% of all testing of trial participants by 2023, says Dr. Nagashima.

Though virtual medical examinations are convenient, patients might feel somewhat detached when not visiting a clinic in person. To solve this, Dr. Nagashima says, “since we are working remotely online, we are conscious of expressing our feelings by smiling, chatting and waving hands, to show that we are close to the patients.”

This show of feeling is reciprocated. “The patients also express their gratitude for the support and encouragement they receive,” says Dr. Nagashima. "The most important thing to remember is that the patient is not the only one who needs to be taken care of."

Mr. Shigeki Tanaka, Head of Japan-Asia Development, Executive Vice President, Astellas Pharma Inc. applauds the initiatives of Tokyo Center Clinic but also expressed concern about whether online medical examination at other facilities will allow each staff member to express themselves naturally with patients, thus successfully implement a patient-centered DCT.

Dr. Nagashima replies, “I think we can do it, and I think we're doing it, but it's not easy to do the same thing in other places. Peter Drucker once wrote that you can't make music if you have only instruments without orchestration. Even if you have the right tools, it’s not going to work.”

He explains, “so we are hoping to have a few more companies join hands with us, then one of them with share their experiences with others. As we repeat the process, we will be able to move from an individualized approach to a manual-like approach.”

It might not be so easy to attract clinics to implement patient-centric DCTs. Mr. Toshiharu Sano, Associate Vice President, Deputy Director of Clinical Operations, MSD KK says, “Japanese people tend to look for reasons why they can't do something and then don't do it, which sometimes leads to delays in introducing new systems. In this context, Tokyo Center Clinic's DCT trial is a good example of trying something new, and it worked better than expected.”

Pharma is working on add-on practical solutions to enhance the patient-centric DCT. Mr. Kazushige Hibi, Director of Clinical Development, Oncology Clinical Operations, AstraZeneca KK, reports on implementing wearable devices in clinical trials. One device monitored heart rate, fluid retention, activity, and sleep status in patients with a history of chronic kidney disease (CKD) and complicated heart failure. A device in another trial monitored heart rate and cardiac activity in CKD patients during attacks.

With the introduction of these wearable devices, several challenges became apparent. For example, older participants in the study had difficulty operating the devices. In contrast, younger participants were reluctant to wear them at work. Therefore, Mr. Hibi concluded that it is important to strike a balance between the expectations of pharmaceutical companies and trial participants. Companies are focused on fewer patient visits and safety monitoring while participants desire a device that is easy to use and wear.

DCT implementation: Human and business requirements

Mr. Taiki Kudo, CEO of Inclusion Partner Inc. provides business scenarios for implementing a DCT, however he stresses that the needs of patients come first. “Reducing costs is not the primary purpose of the DCT, it’s a way of realizing patient-centricity,” he says, Then, cost considerations come into play.

The initial investment in obtaining software, hardware, and other equipment is more expensive for a DCT than for a standard site-centered clinical trial. However, the DCT can enroll more trial participants per site because it can include older, inaccessible patients and others. Also, it requires fewer sites and monitoring personnel, which shortens the trial length, resulting in an overall cost reduction.

Mr. Sano acknowledges that the key to shortening the overall duration of clinical trials is to shorten the recruitment period while keeping overall costs down.

However, with these cost reductions, Mr. Sano asks how the patient-centric business model would affect CROs.

Shigehiro Miki, Representative Director, General Manager - Japan, Parexel International, compares the situation to how continuous advancement in technology drives organizations and their workforce to re-train and re-skill for jobs of the future. There's a paradigm shift. He says, "From a larger perspective, in the medium to long term, we will do what we can and add value to the business," and, "the paradigm shift will eventually expand the range of services that a [CRO] can provide."

Mr. Kudo, Mr. Sano, and Mr. Miki agree that cost factors are complex. A clinical trial is expensive to begin with and how much the cost of one part increases or another part decreases varies according to materials and labor demands.

Again, cost reductions aside, Mr. Kudo says, we need to remain focused on the benefits of the DCT over site-centric clinical trials: to reach to reach patients who couldn't participate in clinical trials and enable shorter trials and faster drug development.

The pandemic brought with it a new model for conducting clinical trials and the need for orchestration, Dr. Nagashima says. It was serendipitous. And he quotes a maxim of Jules Verne, "Anything one man can imagine other men can make real."

Patient-centric DCT trials are the way forward. Others will implement them in time, but the industry needs to promote them, Mr. Sano says. Then they will spread.

**SHirotaka Nagashima**
Director, Center Manager,
Clinical Research Center
**Tokyo Center Clinic,**
**Medical Corporation Chiseikai**

**Shigehiro Miki**
Representative Director,
General Manager - Japan
**Parexel International**

**Minori Niso**
Brand Marketing Director,
APAC Marketing
**Parexel International**

*ends*

## About Parexel

Parexel supports the development of innovative new medicines to improve the health of patients. We provide services to help life science and biopharmaceutical clients worldwide transformscientific discoveries into new treatments. From clinical trials to regulatory and consulting services to commercial and market access, our therapeutic, technical and functional ability isunderpinned by a deep conviction in what we do. Parexel was named "Best Contract Research Organization" in December 2020 by an independent panel for Informa Pharma Intelligence. Formore information, visit our website and follow us on LinkedIn, Twitter, Instagram.

## About Reuters Events

The pharmaceutical division at Reuters Events strives to make Pharma more open and valued. More open so that the strongest ideas and insights are brought to the fore in a transparent, trustworthy manner. More valued by taking an authentic approach to building products and services that matter to patients.

To do this, Reuters Events provides a hub for senior-level Pharma executives, patient groups and other health stakeholders to exchange ideas and observe shifting trends and practices. We actively respond to the aims and interests of our audience, so please get in touch.