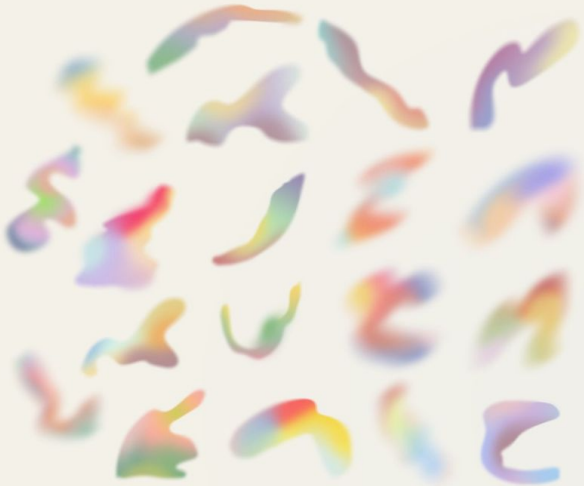
WORKSHOP REPORT: Reuters Pharma Japan 2022

Taking clinical trials to the patient

Clinical trials: Japan's next chapter

By Reuters Events: Pharma Japan 2022



Clinical trials: Japan's next chapter

Post COVID-19, keeping patients at the center of plans for clinical trial design in Japan is vital

Two years on from the start of the COVID-19 pandemic, and patients' lives have been upended. Many gave up visiting hospital even when they did not feel well.

The pandemic and resulting lockdowns, terrible as they have been in so many ways, also served as a valuable testing ground for hybrid decentralized clinical trials (DCTs) in Japan. First, doctors performed medical examinations online for COVID-19 patients. Then, doctors or licensed nurses trained in good clinical practice (GCP) followed up on patients, visiting them at their homes or designated hotels.

While online medical examinations during the pandemic have proven their worth, they don't suit every patient. It's the same with trial design, where the appeal of DCTs is clear but not every trial candidate wants to participate remotely.

What's the best way forward for every patient now?

This is the dilemma pharma and the wider healthcare sector is contending with now. "The idea of not leaving patients behind is a concept that we cherish," says Shigehiro Miki, Representative Director, General Manager - Japan, Parexel International.

The US and EU plan to continue using online doctors to provide medical examinations for their DCTs. But this is Japan, and considering the culture here is paramount, says Dr. Hirotaka Nagashima, Director of Tokyo Center Clinic. In addition, he says we must understand the hopes of patients who are considering participating in the trials.

A neighborhood solution

Catering to the patients' needs is the primary concern, says Dr. Nagashima, stressing the value of face-to-face interactions. But this must be weighed against the opportunity of providing online video conference calls for medical examinations as we emerge from the pandemic, he adds. "If we don't do it now, we might not get another chance."

Catering to patients while also innovating in trials can be achieved by learning from the pandemic with hybrid trials that in many cases brings elements of trials to patients' communities or homes. This hybrid approach would allow in-person visits to patients' homes and online medical examinations, unlike patients' online-only experience in the US and EU.

Dr. Nagashima is now working on partnerships with local clinics and home-visit nursing agencies. As a result, nurses can be dispatched, or patients can visit their local clinic instead of traveling to a large medical institution. In this model, he explains, a trial enrolling 1000 patients might comprise 100 participating medical institutions and 50 neighborhood clinics and home-visit nursing agencies. This approach is convenient for patients since they do not need to visit large medical institutions.

The Tokyo Center Clinic is now moving forward with hybrid DCT design in Japan to study risk factors for cardiovascular events after patients take a preventive drug. The global study will be carried out as a typical DCT using electronic tools for recruitment, screening, consent, investigational product delivery, and online visits with the doctor.

JCR Pharmaceuticals is also implementing a hybrid DCT design similar to that at the Tokyo Center Clinic. After receiving an overwhelmingly positive response from patients and clinicians participating in one study, Mr. Tatsuyoshi Yamamoto, Director of Clinical Operations, believes this hybrid design can work. Thus, the company decided to continue an ongoing study in this new design format, contracting with a local satellite clinic. As a result, his company now considers DCT as a valuable tool to help increase patient participation in clinical trials.

Innovation Dilemma

Hybrid DCTs will not be a solution for all clinical trials, however. For example, Tokyo Center Clinic partnered with local clinics and home-visit nursing agencies in three prefectures to provide home-visit support to patients with a rare neurological disease. But even though it was possible to contract with local clinics, it proved challenging to enroll enough patients because the disease is uncommon. Besides, the local clinics might not have the expertise to provide medical examinations for rare diseases.

In addition, local clinics and home-visit nursing agencies must conform to GCP guidelines. Any participating body would require training programs to meet the criteria. However, "a significant divide exists between academic medical institutions and home-visit nursing agencies," says Mr. Shigeki Tanaka, Head of Japan-Asia Development, Executive Vice President, Astellas Pharma Inc.

Academic medical institutions do not usually provide home-visiting services. Home-visit nursing agencies typically dispatch healthcare assistants to patients' homes and most likely lack the proper training to support clinical trials in new drug development. He thinks there would be few staff with GCP training.

"Training qualified nurses and doctors is the center of any [successful design for hybrids]," says Nagashima. He ensures that all the doctors at the Tokyo Center Clinic understand how to use digital tools to conduct medical examinations. Furthermore, he only contracts with qualified licensed nurses. He provides training on digital tools so that medical staff can report patients' conditions in real-time.

Dr. Nagashima provides a tool to assess local clinics and home-visit nursing agencies. He suggests that a medical clinic carry out a hybrid DCT by contracting with GCP-trained doctors for online examinations, licensed nurses for face-to-face interactions, and DCT coordinators to keep track of personnel and data collected by them. Besides the additional personnel and training, the clinic would need to invest in digital tools. Setting up this kind of clinic also entails a considerable expense, so the ideal situation would be to find funding partners.

Other factors need to be considered besides the expense. For example, some patients feel an invasion of privacy during a home visit and would rather see a doctor at their neighborhood clinic. In addition, he explains that the hybrid method can get complicated if there's a mixture of visits to large medical institutions and local clinics.

Also, patients at home require wearable digital devices, says Mr. Toshiharu Sano, Associate Vice President, Deputy Director of Clinical Operations, MSD KK. But he asks, "What do we do when a device fails?" Waiting for repairs could delay the collection of data, he says. In addition, standard tools among countries would be needed, but they are not standardized now.

There are GCP guidelines to follow, protocols, and tools to conform to it, and medical staff to be trained. Regulations in the EU, US, and Japan must be considered too. Participants recognize that the hybrid DCT design requires careful thought and information sharing. Nevertheless, the pharmaceutical executives are optimistic about realizing GCP for hybrid DCTs in Japan.

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