Remaking Clinical Trials WITH THE PATIENT IN MIND

Tammy Guld, Global Team Lead for Janssen Clinical Innovation, talks about how the clinical trial experience for patients can be improved.

PV: How can pharma companies improve the clinical trial experience for patients and get medicines to market faster?

GULD: There is a shift in how patients are working with companies based on what they expect from their healthcare. Patients want a more integrated clinical trial experience. To meet their needs, companies need to design a connected and integrated experience that engages patients before, during, and after the clinical trial. We need to have a more reciprocal relationship with patients. Digital and voice capabilities, as well as other technologies, are available to support patients so a study is less of a burden. For example, patients don't have to travel three to five hours every week to get to a typical brick-and-mortar facility as is required with a typical clinical trial; these important in-person engagements can now happen only occasionally.

PV: Why is reciprocity important and what does this look like?

GULD: Patients are the end users. The patient is the recipient of the clinical trial experience and, in the end, hopefully a new medicine is being developed for them. It's critical we hear about their insights on their disease so that the study can be created appropriately and with the right design from the beginning. It's also important for us to understand what their experience is throughout the study through frequent surveys to improve patient retention, and ensure we have the highest quality data for regulators to make a decision.

PV: What type of digital tools can make this happen?

GULD: I'd start with using a bring your own device — BYOD — platform that enables virtual trials, which exists today. What is missing, though, is the operational component to set up these platforms. The way in which studies are run using this type of connectivity looks and feels different inside the walls of the sponsor. Innovation teams, such as ours and at other companies, are struggling with how to set up the operational model to support, embed, and scale such capabilities.

PV: Are siteless trials the way of the future in R&D?

GULD: My opinion is that there will likely be a hybrid approach. There are aspects to telemedicine that can be incorporated strategically and for certain populations and for certain types of studies. I don't believe all clinical trials will become 100% virtual.

There are direct-to-patient elements that can be deployed in a very fit-for-purpose fashion, and we need to learn and understand how to operationalize these, and we need to understand how this type of technology can be integrated into clinical trials and into patients' lives. A hybrid approach will continue to gain traction.

PV: Tell us about Janssen's approach.

GULD: We're piloting and taking a very pragmatic approach. We've learned from industry where it would make sense to use such capabilities, which types of studies, what types of patient populations, what durations of treatment, what types of medicines — the factors that influence where to first implement a direct-to-patient approach. We've assessed our portfolio against these criteria and are strategically evaluating our options.

For example, we are currently piloting a virtual trial in the immunology space leveraging real-world data to identify patients. We are also using actigraphy to collect a number of active daily living assessments.

PV: Can you share any learnings from these pilots?

GULD: Our early learnings involve our internal process and on how to get through legal, quality, and privacy hurdles because we haven't conducted this type of trial before. We have found that most of the work involved looking at our internal SOPs and our internal processes to see how they can support this type of study. Some of the key takeaways were around process and not the technology itself.

PV: How has the patient experience improved through these pilots?

GULD: We're gathering that information now. It's a bit too early to say for certain, but we'll share results soon so others can learn. It's an important operational model that has the potential to also improve enrollment, engagement, retention and diversity within a trial. PV

Tammy Guld

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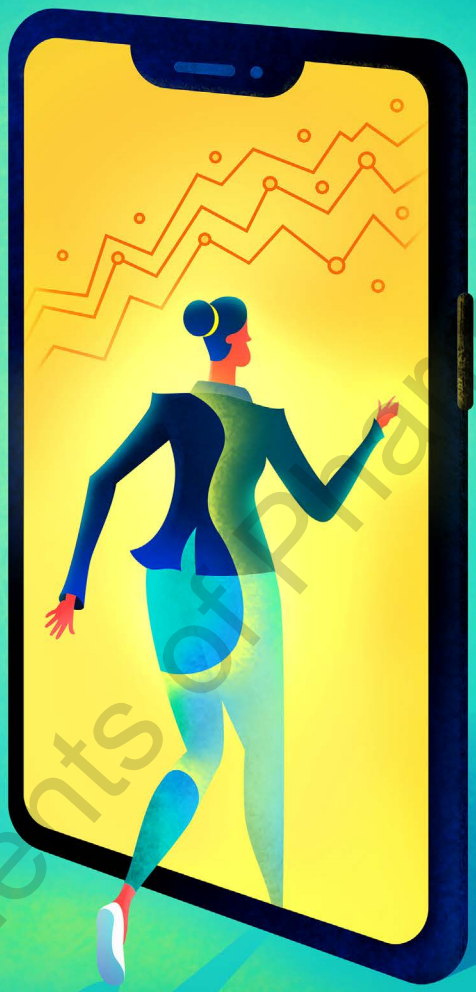

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