The Rise of Patient-centric Clinical Trials in Today's Environment

There is a growing movement within the industry to focus on patient-centricity in clinical trials. For example, the FDA and EMA have introduced requirements to include patient input into protocol design and provide lay summaries to patients at the end of trials. It's becoming more apparent that reducing the patient's burden by putting their needs at the centre of clinical trial development can have great rewards for both the patient and the sponsor. More recently, the COVID-19 crisis has demonstrated the importance of preparing and executing trials in a patient-centric way to ensure they have access to clinical trials, even in potentially unpredictable situations.

Patient-centricity is all about making it as easy as possible for patients to learn about and participate in clinical trials. It's about identifying the challenges faced by patients (often the most practical things like transportation to visits and, in extreme circumstances like COVID-19, global barriers to healthcare access), and then taking steps to reduce these barriers.

Patient-centricity:
Supporting Clinical Operations and Study Adherence

When it comes to clinical trial participation, the main barriers faced by patients are geographical, financial, and practical. In terms of geography, sometimes the patient lives too far away from the study site to make it feasible for them to visit as often as is required for the trial. Data from Forte Research shows 70% of potential clinical trial participants live more than two hours away from their nearest study centre. In this case, we look at ways to make it easier for them to travel to the site or, if it is simply too difficult, we take elements of the study to them by using a decentralised trials (DCT) approach. With the COVID-19 health crisis, we have observed how global situations can unexpectedly impact the ability of patients to physically visit a site, which is another impetus for the increased consideration of decentralised trial approaches.

We created a Patient Innovation Centre to put the patient at the centre of the way we operate in terms of clinical trials. This approach considers each person's life as a whole, rather than just focusing on their time as a patient, and we then take that human aspect into account when we run our trials, which is particularly important as we respond to changing health circumstances that further challenge patient access to new medicines.

Financially, the patient often has trouble covering the cost of getting to the clinical trial site. For instance, it may be too expensive for them to travel to a hospital site as often as they need to, or they can't cover parking costs for the time they're required to be there. We work with them to lift that burden.

And practically, it can be very difficult for a patient to participate in a study with hours-long visit requirements. They must take time off work, arrange childcare, and postpone other tasks and errands necessary for daily living. Here, we can look at those practicalities for the patient and work to reduce the more burdensome elements within the protocol where possible, or support with practical solutions where they are critical to the scientific integrity of the study.

By putting patients at the centre of trial planning and execution, it makes it easier for them to learn about the trial and understand its details so that they can fully grasp what it means for them. It allows them to make a truly informed decision about participation. And once they're in the study, we've already looked at the potential barriers and addressed them so that the trial process is clear and simple, making it a much more positive experience for the patient.

Sponsors Also Reap the Rewards

Patient-centricity benefits our sponsors as well. A simpler, more practical clinical trial protocol enhances recruitment and retention and leads to fewer protocol amendments, which, in turn, reduces trial cost. And if recruitment and retention are going well, there's the potential to get the drug to market faster.

According to "*The Innovation Imperative: The Future of Drug Research*", a report undertaken with The Economist Intelligence Unit (The EIU), drugs developed using patient-centric designs are 19% more likely to launch – they have an 87% chance of launch versus 68% for drugs developed without this approach. And when it comes to recruiting the first 100 participants, patient-centric clinical trials took only four months to do so, compared with the average of seven months for all trials.[1]

Through the Patient Innovation Centre, we proactively seek opportunities to address the needs of commercial stakeholders and build a better value story. In addition, our regulatory experts incorporate guidance to address agency requirements from a patient-centric perspective.

Collaboration with Patients and Caregivers is Key

From the outset, our approach to decentralised clinical trials (DCTs) involves collaborating closely with patients, caregivers, clinical research sites, and patient advocacy organisations. Rather than assuming what the patient wants or needs, we ask the patients directly through global patient advisory boards and Patient Insights Methodology.

Our Patient Innovation Centre uses a combination of web listening and input from patients, caregivers, and site staff to get a clear picture of the key patient and caregiver burdens. We study the way patients talk about their disease and treatment options, elicit direct feedback from patients and caregivers through our patient advisory council, and consult with site staff to understand what is important to them and the challenges they face. From this, we design targeted decentralised trial strategies that take the needs and preferences of patients and caregivers into account and reduce the burden of participation. This can accelerate patient enrolment and supports retention.

To reduce the burden on patients when it comes to trial participation, Parexel's decentralised clinical trials protocol can take parts of the trial to patients in their home. It includes elements

such as online recruitment, home nursing, direct-to-patient drug shipments, patient apps, and sensors to enhance patient experience and compliance.

As a result of the COVID-19 crisis, we have seen a renewed enthusiasm to consider decentralised trials or hybrid approaches. This is particularly from a regulatory perspective, where new guidance is coming out swiftly with a number of agencies proactively stating their preference for a DCT approach to support patients. The key to success in moving to a decentralised approach is prioritising trial standards and consistency to ensure patient safety. Many sponsors are becoming more open to DCTs as they work to maintain patient safety and data quality, and we are working closely with sites and members of our patient advisory council to ensure that we're keeping both the site and patient input top of mind as we shift a number of traditional trials to the home.

Our Patient Sensor Solution service builds and deploys strategies to continuously collect data through the use of sensors that remotely capture, transmit and store data in a secure cloud-based platform. This way, the patients and their caregivers have the research brought to them without the geographical, financial, and practical burdens inherent in traditional clinical trials procedures.

Decentralised trials involve working in close partnership with clinical trial sites. We communicate with investigative site staff so they can tell us where they see trial participation as being challenging for patients, what types of communication will resonate most, and which trial elements can be deployed effectively in the home. This collaboration helps us make the study experience better for patients, so that participating in a clinical trial fits in with their personal circumstances. Our goal is to fit the trial as closely as possible to their regular routine, with minimal disruption to sites. Even before the addition of a trial, patients spend so much time and effort managing their disease; the last thing we want to do is add further complications to their lives.

Listening to What Patients Really Want

By conversing and collaborating with patients, we sometimes find that they want something that has not been considered in the study design. For example, we recently worked on a decentralised trial strategy for a long study with an intense visit schedule. Our initial assumption was that taking the trial to patients in the home would be beneficial, but we always work to test our assumptions with patients directly. So, we interviewed 1500 prospective patients and found that they overwhelmingly preferred to come into the clinic for the visits. They appreciated the extra care and attention from the staff and the close bonds formed through these long and frequent visits.

On another project with a study that required 17-hour site visits, we discovered that questionnaires for patients and caregivers related to an exploratory endpoint were responsible for five hours of those visits. So, we worked with the sponsor to support the adjustment of the protocol, balancing the burden on participants against the scientific needs of the study.

Paediatrics and rare disease studies are two of the areas where we are most active from a patient-centric perspective, often deploying decentralised trials to improve access to care and help patients and their families manage participation as part of their daily lives. When kids are participating in trials, it's very difficult for them to take long periods of time away from school. Parents of a sick child often have other children to care for as well, so it can be problematic for them to arrange childcare for the extended periods required to participate in studies. And, in the case of children with autism or other special needs, it can be extremely difficult, if not impossible, to travel over long distances to reach a clinical site. In those cases, having a nurse visit the home versus having to travel is a game-changer.

Patients Beyond the Clinical Trial

Our work with patient engagement is relentless. We continue to talk with patients through our advocacy group connections, patient advisory council and Patient Insights Methodology projects. Recently, our CEO and Chief Medical and Scientific Officer both joined our patient advisory groups in the US and EU to listen to patient input and understand the patient point of view, helping us to continue to improve the trial experience for patients. We also continue to look beyond the study. How can the patient continue to access the drug when participation ends? When will it be available on the market? How can we help patients understand study outcomes and ways to transition to a post-study treatment plan? How can we continue to support patients through our managed access programmes to facilitate early access to promising new medicines for patients with unmet needs?

Our responsibility doesn't end with that last visit. The patient has given us their time and dedication, so we feel it's important to give them our gratitude and continued attention.

What's Next for Patient-centric Trials

The many benefits to patient-centric decentralised clinical trials are clear. Yet the report found that only about 5% of the Phase II and III trials conducted over a five-year period employed patient-centric approaches. With the advent of COVID-19, companies are quickly rethinking the benefits of considering decentralised or hybrid approaches.

For the most part, our clients agree that patient-centricity is important and that it holds great potential, but they often don't know where to start. Our Patient Innovation Centre can help sponsors to shorten that learning curve considerably and we continue to provide consultancy, partnership and support to continue the development of this critical area of the R&D process.

REFERENCES

1. https://druginnovation.eiu.com/

Rosamund Round

Rosamund Round is Vice President of Parexel's Patient Innovation Center and spends her time devoted to simplifying the patient journey in clinical trials. Focused on the reduction of geographical, financial and practical barriers to study participation, Rosamund is excited by the industry shift towards a truly patient centric approach. Her first job in an oncology clinic at Massachusetts General Hospital (USA), sparked her passion for putting patients at the center of clinical research planning and implementation. Subsequent roles in patient recruitment in both the pharma and CRO industries have enabled her to innovate and explore better ways to communicate with patients. This includes addressing literacy and health literacy, exploring technological advancements, and constantly scanning the environment to help generate new ideas to make clinical trial participation more accessible and convenient. Always looking for the next best thing in patient recruitment, Rosamund is delighted to share her learnings around patient centricity and innovation in patient engagement.

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