Direct-to-Patient Trials – Improving Patient Engagement

Traditional methods of engaging with patients have difficulty keeping up with modern challenges and expectations of convenience, safety, and empowerment. To stay ahead of current trends, trials need to take advantage of patient-reported outcomes

Sarah Halmrast at CSM

Society is evolving rapidly, especially in response to the COVID-19 pandemic. New technologies are changing the way we communicate, and vast amounts of information are readily available, introducing a new era of personalisation. This has resulted in patient needs becoming the focus of clinical studies. With patients taking more control of their own health and treatment options, the advantages and challenges of different trial methods are magnified.

A Patient-Centric Clinical Trial Model

The traditional method of patients visiting their clinical trial site to pick up medication can disrupt the patient's day-to-day life. Today, this can be minimised by sponsors implementing a direct-to-patient (DtP) model into their study design.

With clinical supplies prepared, packaged, labelled, and then shipped directly to the home of the patient or caregiver, DtP ensures that trial participants are no longer required to visit the clinical site, which has become even more challenging in light of COVID-19.

Barriers to Patient Engagement in Traditional Clinical Trial Models

Patient recruitment and retention are two of the main challenges for clinical trials. The average patient dropout rate across all clinical trials is around 30%, which can have a significant impact on trial timeline and success (1).

In traditional clinical trials, the location of a trial site can have an impact on patient engagement. If it is too far from the relevant patient pool, they may not be able or willing to make the lifestyle interruptions needed to take part in the trial. For many patients, especially those with compromised immune systems, a hospital visit can introduce additional health risks.

International Clinical Trials, November 2020, pages 14-16 © Samedan Ltd 2020

Regular hospital visits can also be an intimidating experience. Patients may feel a lack of personal attention or, even worse, feel like they are just a number.

With patients geographically spread out, in need of frequent doses, and a drug product that has strict storage and delivery conditions, traditional study models can present fundamental barriers.

The Impact of COVID-19

The emergence of the COVID-19 pandemic has amplified some of the challenges to patient engagement and introduced new concerns. For a long time – and to a certain extent, depending on the geographical region, still today – people were discouraged from going to hospitals to help prevent the spread of the virus. This created a sense of unease. In some countries, the situation has settled slightly for the time being, but having to go to a hospital site amid this crisis causes many to worry they may get infected.

It is not just patient engagement that is at risk. Clinical trials themselves may also be affected by the crisis. Providing healthcare – especially to patients with COVID-19 – remains the top priority of hospitals, and they may not be as capable of accommodating clinical trials during this demanding time. As a result, studies may slow down, be interrupted, or even cancelled due to the pandemic.

Within the current regulatory framework, DtP shipments have limitations in Europe. However, DtP investigational medicinal product delivery from site to trial participant is now accepted in several EU member states due to COVID-19. Even DtP from depots to patients has been accepted by authorities in rare cases when justified.

Engaging and Empowering the Patient

Eliminating the detractors of participating in a traditional study helps to improve enrolment and retention and empowers the patient. By removing the need to travel, DtP helps minimise the impact of the trial on the daily lives of patients. It also opens up trials to bedridden/homebound patients and minors, who may otherwise have to spend weeks at a trial site when specific sites are few and far between.

With DtP, study participants can receive their medication without having to take time off work or worrying about disclosing their condition to others as a result. This model also alleviates the pressure on family members who may need to transport their loved one to the dispensing site. It also reduces the costs involved with taking part in a trial as patients do not need to pay expenses related to travelling to a site, such as fuel, parking, public transport, meals, and, potentially, lost wages.

The flexibility DtP provides ensures that the treatment can be administered at the patient's home, office, or vacation destination. It puts the patient in charge of his or her own schedule, and removes the burden on them to remember to go to an appointment.

Administering the drug at home is more comfortable for the patient than being in a hospital or doctor's office. It also reduces the health risks involved with going to a hospital, especially for those with a compromised immune system.

Choosing the Right Method

With patient engagement in mind, different DtP models have a variety of different benefits.

Depot-to-patient shipments ensure that patients receive their medication and remain healthy, without disrupting their lifestyle, and reduce the impact on clinical trial sites.

Site-to-patient shipments introduce more involvement at the site level, which may increase communication between the provider and patient, ensuring the patient maintains a connection with someone.

Considering that not all patients are the same, and not all will want shipments to their location, a hybrid design can focus on what is best for each patient rather than what may be considered best for the patient population of that study.

All of these factors translate into a greater willingness to participate in a trial, thereby improving patient recruitment and patient retention.

Benefitting from More Advanced Medical Research

DtP allows sponsors to target those with rare diseases or conditions. Trials can also focus on a broader and more diverse population base, including patients living in rural locations and patients with a lower income level – who can be more sensitive to financial expenditures (2).

The benefits for trial participants are, therefore, significant, as DtP models can lead to better-quality medical research. Improved trial participant retention may reduce the amount of missing data, improve data interpretability, and shorten clinical trial timelines (3). Faster participant recruitment can accelerate patient access to important medical treatments.

An individual logistics plan for each patient, which factors in their address, and which couriers or flights could be used to ship the drug product, ensures a smooth delivery and compliance.

DtP also makes clinical trials possible for products with specific logistical requirements. Drug products that need to be reconstituted have a shorter time window prior to dosing to retain drug efficacy, which precludes patients from picking up a multiple day supply from the site and dose at home. Such restrictions make DtP

a particularly suitable model for this type of trial.

Leveraging innovation, such as remote monitoring and wearables, can further improve the patient experience. Virtual interaction between physicians or other qualified health professionals and patients can maintain the patient/doctor relationship by ensuring face-to-face communication to address any concerns that may normally have been discussed in a clinic setting under a traditional trial model.

Key Considerations

There are evidently many advantages to DtP, however, we must also address the challenges. First of all, it requires having a strict distribution model. Time frames need to be clearly communicated by all parties to ensure the patient is available on the scheduled delivery date. Maintaining specific temperature requirements during transit is essential to ensure drug integrity. In addition, patients need to be educated to manage the dosing themselves.

Secondly, patient data are handled by many parties, which can raise patient confidentiality issues. Ensuring compliance with the Health Insurance Portability and Accountability Act and GDPR can be a logistical challenge. Laws not only need to be respected, but interpreted and used with the patient's safety and needs in mind. Finally, one should not underestimate the fear of change. Decision makers become accustomed to certain budgets, practices, and timelines. Changing these can be stressful because a potential lack of success is likely to be blamed on that change, whether or not it was the cause.

Working together with an experienced and specialised service provider that is an expert in the field will help to mitigate the challenges and make that transition period as smooth as possible for all parties. It will be able to adapt to the unique needs of each project and, most importantly, those of each patient.

Why Change Matters

Without making changes and facing the challenges, ensuring clinical trials are more patient-centric will continue to be an obstacle for the pharmaceutical industry.

Within the context of COVID-19, the benefits of a DtP model become heightened: removing the stress of having to go to a hospital, getting the medication to patients safely, and taking pressure off hospitals currently focused on treating infected patients. The flexibility required and shown by the pharma industry to adapt to this crisis and ensure the continuity of clinical trials has demonstrated that a more efficient model is not only possible but also feasible to implement.

Each patient has their own story, and by opting for a model built around the patient's needs and experience, the patient, and, ultimately, the sponsor and the trial will benefit. In parallel to improved patient engagement, implementing a DtP model will support medical advances, improve access to treatments, and enhance the lives of patients as a whole.

References

1. *Visit: vertassets.blob.core.windows.net/download/64c39d7e/64c39d7e-c643-457b-aec2-9ff7b65b3ad2/rdprecruitmentwhitepaper.pdf*
2. *Unger JM* et al, *Impact of the year 2000 Medicare policy change on older patient enrollment to cancer clinical trials.* J Clin Oncol *24(1): pp141-4, 2006*
3. *Visit: www.ctti-clinicaltrials.org/projects/decentralized-clinical-trials*

Sarah Halmrast has 20 years' experience in project management, primarily in clinical supplies. She initially joined **CSM**, which later became part of Clinigen Group, as a pharmacy technician and held various roles within the company before becoming the Vice President, Global Project Management, in 2018. Leading the Project Management departments in the US and the EU, her role is critical to ensure harmonisation of practices for clients to experience the same service levels, regardless of their geographical location. Sarah has a Pharmacy Technician degree from North Dakota State College of Science, US, and a Bachelor's degree in Business Management from the University of Mary, US.

shalmrast@csmondemand.com