Amplifying The Patient Voice To Build More Inclusive Clinical Trials

In the clinical trial ecosystem, patients are imperative to successful research. Without enrollment, engagement, buy-in, participation, and retention, studies are simply unviable. After many years of investment of both time and finances into R&D activities, being unable to complete this stage of the process is disheartening to all stakeholders involved. Studies have shown only about 30% of clinical trials will meet enrollment goals and timelines.

The impact of this failure in the process on trial sponsors cannot be underestimated, according to Scott Gray, CEO of patient concierge services provider, Clincierge. Gray states, "The biggest consequence is the trial could fail. If it cannot be conducted, all of the R&D money spent leading up to the point of being able to do human trial testing is lost." Even if trials ultimately succeed, the costs of delays are significant, even ruinous, for some companies. Gray shares loss estimates of between $600,000 to $8m for every day a study is prolonged.

SCOTT GRAY, CEO, CLINCIERGE

These risks can be mitigated by taking a patient-centric approach to clinical trials. However, existing barriers to participation must first be overcome.

Navigating Financial, Travel, And Support Challenges

Identifying a patient for a clinical study is only the beginning of ensuring their ability to participate in and ultimately complete the trial. Firstly, there are various financial implications to consider. Patients may need to take time away from work to visit clinical sites and receive treatment in a study, and the cost of travel in itself can be significant, depending on the trial location. Even if these expenses are reimbursed, patients may not be in a position to make the initial payments necessary to participate.

There are also logistical barriers when traveling to sites, and Gray notes patients have a number of questions when considering their participation. "They ask: 'Is there a site that is near, or do I have to drive across town, the state, or even to another state? What is the duration of the visit and follow-ups?'"

These unknowns require advance planning, which may dissuade patients from participating. Moreover, some disease states may impact mobility or cognition, compromising a patient's ability to travel.

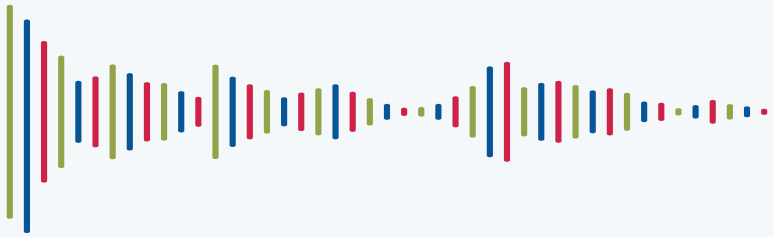
In a study conducted by Clincierge, 62% of patients and 59% of caregivers stated that travel-related challenges, and their subsequent financial implications, prevented them from taking part in a trial. Unfortunately, it is not feasible to ensure all patients within a study can avoid long journeys to participate, especially in indications such as rare diseases where populations may be spread globally.

It is, therefore, critical to support patients by arranging their travel and removing the immediate financial burdens of participation. "We have designed Clincierge's services to solve this challenge, making purchases on behalf of the patients and coordinating the logistics so they can get to the site easily," says Gray.

The Impact Of COVID-19

Study operations were significantly impacted by the COVID pandemic, with new, decentralized trial models implemented to continue research when travel was restricted, and clinical sites were closed. The success of decentralized clinical trials (DCTs) has been met with excitement from the industry, as they can significantly reduce the travel burden on patients. In some instances, site visits can be replaced with in-home visits from health care workers, while mobile technologies can be utilized for remote patient monitoring.

While DCTs undoubtedly offer benefits for patients in certain circumstances, Gray stresses they are not a one-size-fits-all solution and must be structured with the patient experience at the top of mind. "Interestingly, we have discovered there are patients who do not want site staff visiting them at home. For example, we saw in many instances with Alzheimer's patients, their only social experience out of the home was when they went to the trial site and interacted with the team," he notes. Moreover, there are many rare diseases where specific tests such as MRIs are needed and cannot be conducted in the home.



Innovative thinking was needed during the pandemic for studies where decentralized models were not applicable to ensure patients could remain enrolled in trials. There are several examples Clincierge experienced which stand out to Gray. "In one instance, the Spanish rail and bus system was shut down. We hired a private car to pick up the patient and drive them across the country and arranged overnight hotel accommodations for both the patient and the driver. In a separate instance, there was an immunocompromised patient who had their final site visit, and we sought authorization for private air travel to transport them. It was extremely important to the patient that after many months of participation, their data could be included and make a difference in the trial."

The Human Approach To Patient Support

These examples show the benefits of a patient-centric approach to clinical trials. Such solutions are only achievable by offering individualized services considering each participant's circumstances. This human touch is at the heart of Clincierge's ethos. "Our coordinators work one-on-one, person-to-person, through all of the logistical and financial obstacles which could prevent the patient from participating or cause them to drop out if these burdens were directly put on them," says Gray.

This concierge level of service is of paramount importance, especially given the stresses already upon patients suffering from a disease warranting clinical intervention. Clinical trial participation comes with a whole host of considerations outside a patient's day-to-day life; managing these logistics without support would be untenable. Gray continues, "Everyone needs a place to call for help. Let's say they are trying to use a system to request transportation to the site. Think of their emotional state at the time. They are struggling with a disease, and now there's a device or software that is frustrating them. A phone call is favored so they can talk to someone."

The data speaks for itself when comparing trials offering one-on-one patient support services to those that do not. Retention rates for studies supported by Clincierge are well over 90%, where the average rate is usually less than 70%.

The Importance Of Inclusivity

The benefits of trial accessibility on patient experience are obvious and are all part of a bigger picture for the success of treatments. Enabling more patients to participate in research, regardless of socio-economic background or demographic group, ensures treatment efficacy and safety across different genetic makeups.

Regulators such as the US Food and Drug Administration (FDA) have identified trial diversity as a critical area for improvement, as study populations notoriously lack appropriate representation from different socio-economic groups. Gray notes that traditionally, 60%-70% of study participants in the United States have been white males, primarily because they can afford travel costs and time away from work. The African American, Hispanic, and Asian American communities account for 13.4%, 18.1%, and 6% of the US population, respectively, yet they account for only 5%, 1%, and 1% of trial participants. "It is a huge challenge, and lots of work needs to be done to level the playing field, so we get better outcomes data across the spectrum of genetic makeup," he states.

By taking a human-centric approach to supporting patients, opportunities to participate in clinical trials are made as inclusive as possible. This move towards inclusion will be imperative as diversity requirements in drug development become more stringent. However, these guidelines will also ensure the patients' experiences are positive and they stay engaged in the trial throughout. Increasing retention rates is the key to expediting drug development and achieving a return on investment from the many years of R&D prior to the beginning of the clinical trial phases. Gray concludes, "If you are able to get your outcomes data on time, you can submit for approval sooner and go to market to begin recovering huge R&D investment and provide treatment for other patients. That is the biggest factor of why we feel this human-to-human connection is essential."

"If you are able to get your outcomes data on time, you can submit for approval sooner and go to market to begin recovering huge R&D investment."

Scott Gray, Clincierge