White Paper

roundtrip

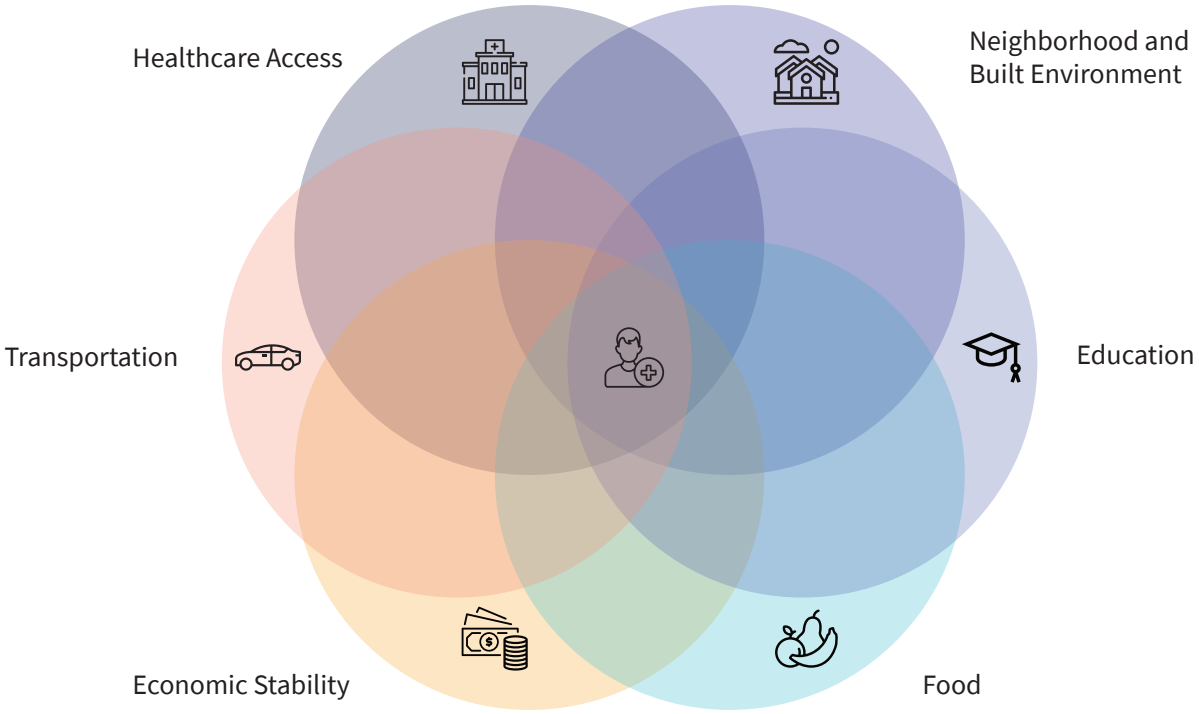
Transportation and Clinical Trials

Abstract

The importance of clinical research cannot be understated: clinical trials are vital to medical innovation. The treatments that are now standard of care were once regarded as cutting-edge, and all of them were established through clinical trials. As the proving grounds for tomorrow's treatments and therapies, clinical trials also play an essential role in the discovery of new diseases as well as new ways of detecting, diagnosing, and preventing them. Clinical trials are also important for uncovering suggested treatments that don't work and may even have adverse effects on patient health.

Considering the significance of clinical research, there is an ongoing disconnect when it comes to patient recruitment and participation. An article published by ZS reveals that "clinical trials typically last 42% longer than expected in phase I, 31% longer in phase II, and 30% longer in phase III, mostly because of recruitment delays." According to an article published in December of 2019, The Michael J. Fox Foundation launched a survey in 2017 to assess the need for transportation infrastructure at clinical trial sites. From that survey, "transportation considerations were identified as a major barrier to participation and retention in clinical trials."

Clinical trial participation is especially low for specific populations, including adults age 75 or older and people of certain racial backgrounds (FDA). As drug safety and efficacy can vary across demographic subgroups, clinical trial populations



While there are many social determinants of health, this image illustrates their related nature. Where a person is likely to experience one barrier, it is likely they are also experiencing other barriers too.

must endeavor to reflect the targeted population of users of the medicines.

With many people citing transportation as a barrier to healthcare, providing transportation to clinical trials has the potential to increase inclusion, ultimately making a positive difference in trial results and speed for treatments to reach the market.

Challenge

There is an ongoing disconnect between the importance of clinical trials for innovation and patient recruitment and participation in them. This issue is compounded by the challenge of widening clinical trial diversity to produce scientifically robust results. Transportation factors are a major barrier to both participation and retention in clinical trials, particularly those of specific demographic groups.

Introduction

When we typically talk about transportation barriers as a part of the social determinants of health (SDOH), we generally focus on how they impact health outcomes as they stand today. In reality, these barriers are also impacting the health outcomes of the future. If you are a patient who is eligible for a clinical trial, as well as one of the 3.6 million people in the United States who miss or delay a medical appointment due to a transportation barrier every year, how do you get to a clinical trial, repeatedly, sometimes over many months at a time?

Despite their level of importance for medical innovation, both pharmaceutical companies and CROs face huge hurdles recruiting patients and sustaining their involvement throughout the trial. With any clinical trial, a committed level of

participation is contingent on obtaining reliable results, and reliable results are necessary for producing viable treatments and therapies. In addition to the participation challenge, clinical trials also face difficulty retaining participants. According to a report by the Center for Healthcare Innovation, "in addition to the patient recruitment problem, increasing clinical trial costs are also attributed to patient retention challenges. Recent reports revealed a 30% dropout rate across all clinical trials." Moreover, it's important to consider the barriers that influence participation in these studies and how they can be overcome.

According to the Eliminating Disparities in Clinical Trials Project (EDICT) "unreliable transportation and living in remote areas may prevent many otherwise eligible patients from participating in clinical trials." Some low-income groups have decreased participation due to competing issues such as unpaid work leave and lack of childcare. As with many challenges in healthcare, increasing and maintaining clinical trial participation is complex. Transportation is not a panacea; there are many aspects of these challenges that will need a variety of different solutions. As for getting patients to the door, providing non-emergency medical transportation (NEMT) is a solution for clinical trials to make progress with patient recruitment, participation, and, ultimately, getting medications to the patients that need them.

Background

As defined by the NIH, "clinical trials are research studies performed in people that are aimed at evaluating a medical, surgical, or behavioral intervention." Generally speaking, the results of clinical trials provide evidence for the safety and efficacy of new medicines. Bearing in mind that safety and efficacy can vary across different subgroups, including sex, age, race, ethnicity, lifestyle, and genetic background, clinical trials need a diverse constituency of participants to prove how generally safe and effective a new medicine is (Clark, et al.). On the whole, clinical trial recruitment and participation is an access problem across all populations. In the article, *The Role of Clinical Trial Participation in Cancer Research: Barriers, Evidence, and Strategies*, researchers lay bare a few of the myriad challenges related to patient recruitment and participation in clinical trials:

> "To participate in a clinical trial, patients must first have access to a cancer clinic. Access to a clinic can be influenced by many different structural factors such as transportation, travel costs, access to insurance, and availability of child care. Uninsured patients, in particular, present with later stage of disease and have worse cancer outcomes. To the extent that such patients present at their cancer diagnosis with a greater comorbid burden, their likelihood of eventually participating in a clinical trial is lower" (Unger, et al.).

The statement above only applies if you know of the existence of a clinical trial. One significant barrier is patient awareness of clinical trials' availability. In a Harris Interactive Survey of 6,000 cancer patients, 85% said they were unaware that participation in a clinical trial was even an option. Seventy-five percent said that if participation in a clinical trial had been offered, they would have been receptive to participating" (NCBI). Groups such as the elderly and rural populations often lack awareness of clinical trials given their low online presence (NIH). And if you do know about a trial's availability, there's a chance that you also might not know that it can benefit you by participating in the trial. Francis S. Collins, M.D., Ph.D., Director of the National Institutes of Health, shares how the critical need for trial participation is compounded by this lack of awareness, as well as how participation can benefit the patient:

> "If clinical trials are to be successful, it is critical that more people get involved. We need to spread the word about the value of participating in clinical trials. Signing up for a clinical trial may indeed benefit medical research and help future generations. But it is not strictly an altruistic endeavor. In many instances, trial participants do gain personal advantages, such as improved disease outcomes or better health. And we should not be shy about telling that story" (Collins).

Another access challenge comes from the socioeconomic status of potential participants. A patient's awareness of the availability of a trial is subject to the patient's connection with the medical system. If a patient is already at a disadvantage connecting with healthcare because of various socioeconomic factors, then their awareness of trial availability is not going to be the same as someone who is facing better socioeconomic circumstances. As the NCBI puts it, "higher socioeconomic status is associated with having the resources, knowledge, and motivation to seek information about a disease, including access to clinical trials" (NCBI). Conversely, people who are of lower economic status may lack the resources, including transportation, to access a clinical trial. And bearing in mind that the Trump administration is proposing $1 trillion in cuts to Medicaid, including its NEMT benefit, what resources there are may soon be gone.

It is a well-documented fact that socioeconomic status has a significant impact on the lives of many ethnic and racial minorities in the United States. Observe the following quote from the report *Ethnic and Racial Minorities & Socioeconomic Status* published by the American Psychological Association:

> "Racial and ethnic minorities have worse overall health than White Americans. Health disparities may stem from economic determinants, education, geography and neighborhood, environment, lower-quality care, inadequate access to care, inability to navigate the system, provider ignorance or bias, and stress" (APA).

It's no surprise then, that even though nearly 40% of Americans belong to a racial or ethnic minority, clinical trial participants are usually white Americans. In some trials, white Americans make up 80-90% of the participant pool (Scientific American). Historically, 95% of all clinical trials have exclusively featured individuals of European ancestry (Fox). Such an imbalance has major implications for the patient population in the United States:

> "The symptoms of conditions such as heart disease, cancer and diabetes, as well as the contributing factors, vary across lines of ethnicity, as they do between the sexes. If diverse groups aren't part of these studies, we can't be sure whether the treatment will work in all populations or what side effects might emerge in one group or another … The shortfall is especially troubling when it comes to trials for diseases that particularly affect marginalized racial and ethnic groups. For example, Americans of African descent are more likely to suffer from respiratory ailments than white Americans are; however, as of 2015, only 1.9 percent of all studies of respiratory disease included minority subjects, and fewer than 5 percent of NIH-funded respiratory research included racial minorities" (Scientific American).

This is an alarming conclusion; in 2018, the median estimated cost of a clinical trial varied between $12 million and $33 million, with the most expensive trials (some estimated up to $345 million) being conducted for new drugs that were similar to drugs already available and already proven in treating serious illnesses (ISMP). Given the amount of money that is currently being expended on clinical trials, society should be able to easily overcome any real or perceived funding challenges that might be associated with getting rides for potential participants.

The survey conducted by the Michael J. Fox Foundation focused on overcoming transportation barriers because those with Parkinson's disease may face unique barriers getting to and from clinical trial sites: "including dementia, loss of driving ability, timing of medications, impact of reduced mobility, and bowel and bladder concerns." The foundation contacted 843 clinical trial sites in the U.S to participate in a survey to understand how transportation access impacts participant recruitment, and what kind of transportation participants would find most helpful:

> "Of the 49 sites that responded, 95% reported that transportation infrastructure would improve recruitment efforts, and 63% felt it would ensure all studies recruited on time. Eighty-four percent of respondents reported that a taxi, livery, or ride-sharing service partnership would be the preferred transportation infrastructure" (Gibaldi, et al.).

And even though the findings indicate that transportation is overwhelmingly seen as a solution for clinical trial recruitment and retention, it's estimated that only 44% of all clinical trial sites offer free transportation assistance to their participants (Lau).

Solution

There are many ways that easing the burden of transportation for the patient can support participation and retention in clinical trials. According to *Clinical Trial Diversification Better Practices*, clinical trial populations are rarely reflective of the target population who will use the medicine, and addressing the lack of diversity in participants is constantly a challenge for trial sponsors (TransCelerate). In the article, *4 Questions AbbVie Asked To Create More Diverse Clinical Trials* by Charlotte Owens, M.D., one suggestion the author makes for the organization directing the trial to conduct them in the locations where patients are already getting their care:

> "You must consider not only where the study sites will be, but also consider the challenges people may have getting to the clinic. In many communities, people often use public transportation, which may involve transfers and schedule challenges. Consider placing your study sites close to your patients' homes or near a transportation hub to make access easier. Our team also offered transportation assistance, because the cost and inconvenience of an extra ride or two each way for each visit could become a significant barrier for some." (Owens).

Conducting trials in familiar locations for the patient is one solution that may successfully increase participation, but for certain populations, it might not be feasible to expect them to be able to navigate a public transit system without additional obstacles. This is especially relevant for elderly patients seeking to participate where "to use public transit most people must walk to and from bus or train stops, adhere to strict schedules, wait outside for pickup and be able to navigate stairs" (Connolly). Patients participating in clinical trials may be balancing concerns about their health and their potential physical limitations. Paying for ongoing rides to the trial site in addition to whatever medical expenses they may have is likely a deterrent from participation. Unger suggests that covering excess costs for participants is a plausible approach to removing enrollment barriers:

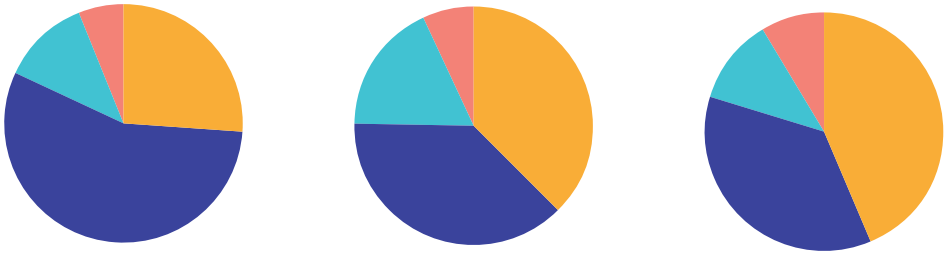
> "If marginal direct costs are prohibitive for some patients, then measures to cover these costs would remove a critical barrier to enrollment. One approach would be to cover the excess costs of clinical trials for all patients, because even in an insured population, copays and coinsurance have been shown to deter clinical trial participation" (Unger, et al.)

While compensating participants for time and travel is one approach, the authors of the study, *Increasing Diversity in Clinical Trials: Overcoming Critical Barriers*, suggest that providing transportation is among the logistical solutions that patients and investigators would most appreciate:

> "Solutions related to logistical considerations that resonated with patients and investigators included **providing transportation**, flexible hours for patients, appropriate compensation, and mobile technology support such as an app for patients and cell phones for those who do not have one" (Clark, et al.).

If clinical trials need greater inclusion, then there should be a more considerable effort to create solutions that curtail exclusion. In 2018, the FDA published an article on its website, calling for more participation and diversity in clinical trials. Though the FDA does not usually conduct trials, it "relies on the data from these trials to determine whether medical products are safe and effective." According to that article, "certain populations can be more at risk for certain diseases—such as diabetes and heart disease—than others. So it is important for patients in those populations who are more likely to be treated for a condition to be included in a trial" (FDA).

Race/Ethnicity of Health Access Areas in Philadelphia



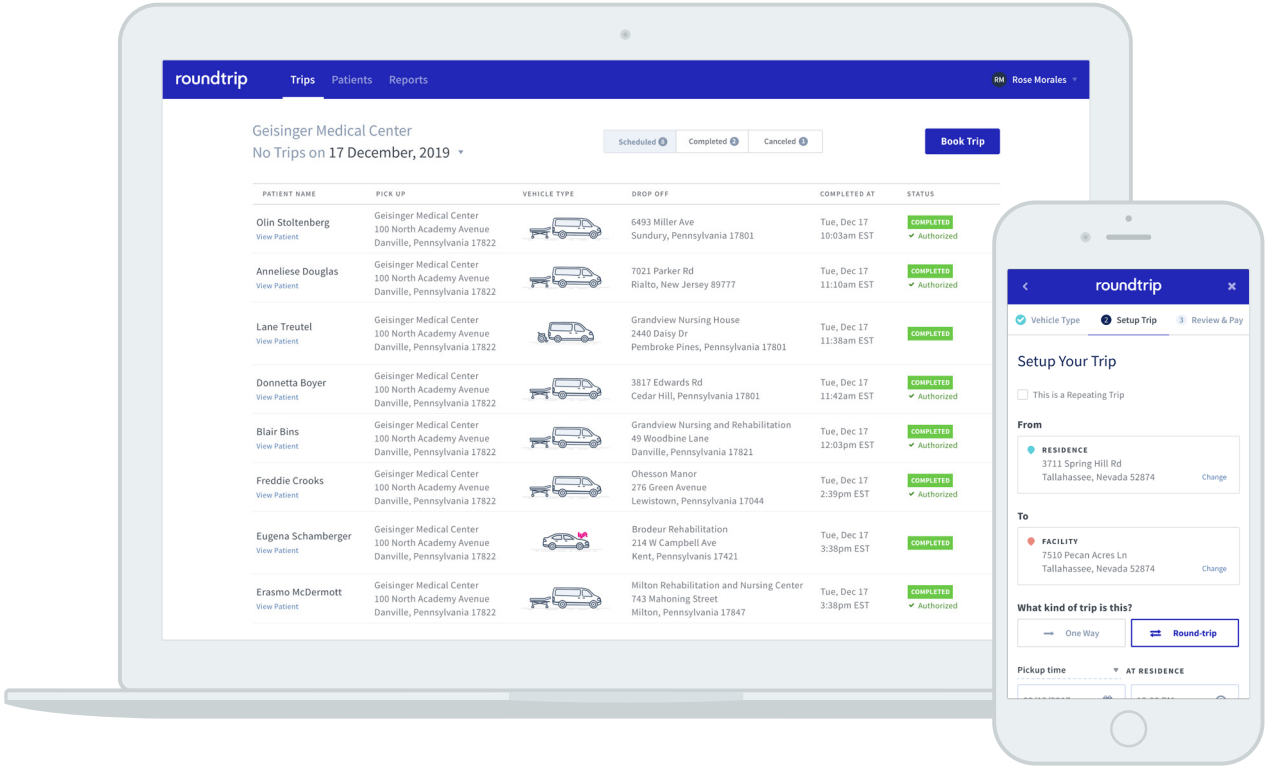
	Lower Access	Moderate Access	Higher Access
Asian	5.9%	6.8%	8.4%
Hispanic	12.0%	17.5%	11.4%
Black - Non Hispanic	55.3%	37.2%	35.4%
White - Non Hispanic	26.0%	37.3%	43.0%

Source: Philadelphia's Access to Primary Care Report for 2018

In Philadelphia, which across a 50-mile radius accounts for approximately 11% of all actively recruiting clinical trials in the United States, there is an ongoing disparity as it relates to access to primary care. *Philadelphia's Access to Primary Care Report for 2018*, says that the leading predictor of primary care access is race, ethnicity, and household income. Even though the number of hospitalizations that are potentially preventable with timely access to primary care continues to decline, the rates are more than twice as high among non-Hispanic blacks and Hispanics in Philadelphia. Beyond Philadelphia, where these predictors are present, there is a correlation for enrollment in cancer clinical trials:

> "Studies have shown that patient populations with historically lower financial resources, including uninsured and minority patients, are often underrepresented in cancer clinical trials. Similarly, patients with higher socioeconomic status seem to enroll in cancer clinical trials more frequently. These disparities in clinical trial enrollment have important downstream effects, which contribute to the lack of data about the impact of certain therapies on patients seen in real-world practice" (Nipp, et al.).

When some trials are estimated to cost up to $345 million, we simply can't afford to undermine the safety and efficacy of new treatments and therapies by leaving people on the sidelines without a reasonable way to get there. Considering that many people who fall into these subgroups are eligible for Medicaid, where transportation is likely to be cut as a benefit, the need for diversity in clinical trials indicates that the benefit should be considered for expansion. Providing transportation to and from clinical trials for participants is an approach that will have an undeniable impact on clinical trials. Widening the circle for more patients to participate in clinical trials, will ensure that medicines are both safe and effective for all people, and ultimately the potential for new treatments and cures to be introduced to the market with greater expediency.



Conclusion

Until recent years, clinical trial sponsors were not under as much regulatory pressure to ensure that clinical trial populations reflect the disease state. (TransCelerate) Now that FDA guidance is clear that diversity is critical in scientifically robust clinical trials, transportation is a key mechanism to overcome recruitment and retention barriers. As more trial sponsors and clinical research organizations follow this guidance, they will need to pilot more transportation programs or systems to provide options for patients to access trials.

Roundtrip can help implement a successful transportation program to increase clinical trial participation and retention. An ideal transportation program will need to be safe and cost-effective while also providing a positive passenger experience. Beyond that, a successful program will require simplified ride coordination through a straightforward booking process, with the auxiliary support of automated trip reminders, and the availability of on-demand and scheduled transportation with a wide coverage area — expanding access for those in rural areas. It will also call for the ability to involve multiple modes of transport to meet individual mobility needs. And to monitor the success of the program, it will necessitate robust data for insight into factors like ride history, total spend, on-time performance, patient adherence, and utilization. Our digital transportation marketplace connects patients with non-emergency medical transportation such as rideshare, medical sedans, wheelchair vans, and stretcher vehicles exactly when and where they need it, and provides the support needed to increase participation and retention in clinical trials.

Contact Us

Let us show you what Roundtrip can do for your patients and members.

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