Clinical Trials & Travel Tribulations:

Improving Access and Outcomes for Patients and Caregivers, Sites and Sponsors

In this paper, we dive into the logistical and financial challenges which increasingly impact all clinical trial stakeholders – from patients and sites, to sponsors and contract research organizations (CROs). Yet with proper planning and the right partners on board, travel arrangements and reimbursement programs can make the trial and patient experience more comfortable and successful for everyone.

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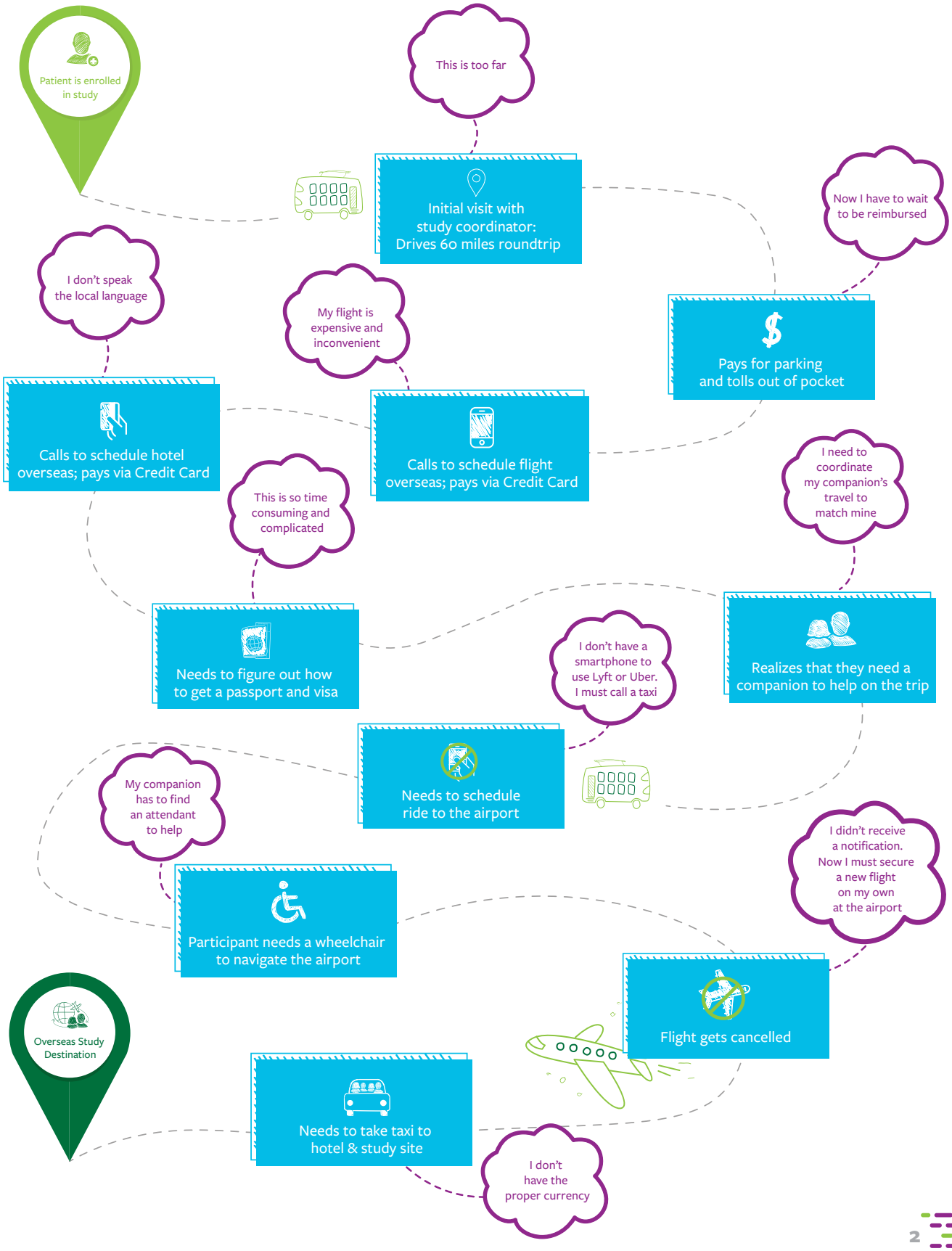


The Journey to Improving Clinical Trial Travel Begins Today

Clinical trials explore ways to improve a person's quality of life. Yet too often for patients, travel to and from the trial has the opposite effect.

Travel in general can be stressful. Roads and highways are jammed with traffic, flights are changed, luggage is lost and airline gates may be far from connections. Travel and the accompanying stressors are magnified for people living with a disease or condition who participate in clinical trials.

The Lazarex Cancer Foundation reports that their patients travel an average of 544 miles round trip for their cancer treatments.

Long distance and even "local" travel within a state or region can create logistical and financial barriers to participation in clinical trials. Frequent visits to the study site and out-of-pocket costs are burdensome. Patients and families may travel great distances to and from study centers. Transportation is especially challenging for elderly participants, yet, regardless of age, lengthy travel times may hamper participation. In addition, clinical trial companions – including family members or medical professionals who speak local languages – may need to accompany patients traveling to clinical study sites.

Furthermore, a fundamental paradigm shift is underway regarding how medicine today is practiced and delivered. Medicine is becoming more personalized, with physicians using tests to identify specific genetic biomarkers that help to determine the best treatments and procedures for each patient. Personalized medicine targets prevention, diagnosis and treatment that is unique for each patient. As the healthcare system transitions from a "one-size-fits-all" approach toward this new approach, access to care will be affected and patients will need to travel greater distances to engage with a site that can treat their specific illness.

Patients and Caregivers

Participants in clinical trials have a lot to worry about: their health, physical limitations, and special requirements. Travel and necessary accommodations including out-of-pocket costs for meals, parking, tolls, etc. understandably add to the burden for patients' caregivers who often travel with them.

Distance/Logistics Planning

Despite the potential benefit of new treatments or medications, distance to the clinic makes participation in clinical trials inconvenient or even unattainable for certain populations, in particular, the elderly, or children. Where patients reside may also affect participation. For example, those in rural areas may have limited access and awareness to available clinical trials.

When the distance to travel for a clinical trial spans countries and continents, another level of logistical complexity confronts patients and caregivers in flight arrangements, language and cultural differences, identification needs (passport and visa), and planning itineraries for car service and hotel accommodations. In many cases, participants have not traveled long distances and as a result, these logistics are commonly cited hurdles for clinical trial participation.

Out-of-Pocket Costs

There is an economic impact, as well, for patients and caregivers who are required to take time away from work in order to participate in a study. This is evident in both expenses for travel (e.g. gas, tolls, parking, etc.), but also in lost wages, especially for hourly workers. Childcare needs may also increase with more time away from home.

When clinical trials are conducted in other countries, expenses go up. Hotel stays and airfare have costly price tags and contribute to financial burden. With chronic conditions and cancer, financial toxicity may affect patients and their families. Routine care for patients with cancer may result in substantial economic hardship with skyrocketing out-of-pocket expenses and risk of bankruptcy. When patients and clinicians discuss the possibility of clinical trial enrollment, they must also consider the potential economic consequences of trial participation. This may dissuade patients from enrollment, making it more difficult to recruit the appropriate number of participants. Removing the need for participants to pay out-of-pocket for travel can alleviate these concerns.

Programs that have implemented participant reimbursement for trial-related expenses (travel and lodging) have revealed a positive impact on patient enrollment and retention, providing access to those from varying socioeconomic backgrounds – benefitting those who may be at high risk for experiencing financial burden related to trial participation. These burdens often preclude their ability to stay enrolled in a study for extended periods of time.

> *There is a huge untapped market of people living with chronic illness/rare disease who would be willing to participate in a clinical trial, but financially do not have the capability.*
>
> *- Christine Von Raesfeld, Clinical trial participant and patient advocate*

Sites

Oftentimes taking a patient-centric approach can lead to increased clinical trial participant satisfaction. However, delivering an optimal patient experience through expanded convenience services has the potential to increase the administrative burden on sites. Adopting new solutions can streamline resource-intensive tasks, remove out-of-pocket costs for sites and patients and improve the overall trial experience for all study stakeholders.

80% of sites say that quality patient transportation is important for recruitment and retention.

- 2018 Society for Clinical Research Sites + Greenphire Research

Patient Recruitment and Retention

Clinical sites have altruism at heart with the goal of being an important contributor to research, while providing the best experience for patients. While there are many hurdles to overcome including protocol complexity, compliance, reimbursements and timelines, a recent Society for Clinical Research Sites – Greenphire® survey of 527 sites revealed that recruitment is the biggest hurdle in conducting clinical trials.

Coordination of travel across markets by site staff occurs quite frequently as sites are responsible for ensuring patient engagement, satisfaction and retention throughout the study. Solutions that remove logistical challenges and provide quality transportation may make a difference. This was the case for MidLantic Urology LLC, an organization who was using a single driver for all trial participant pick-ups. This proved to be inefficient and unsustainable. They switched to using cab rides for participants instead, but this was expensive and unreliable.

Cheryl Zinar, Director of Clinical Research at MidLantic Urology collaborated with Greenphire to orchestrate the introduction of rideshare into her clinic through the integrated ClinCard® portal. The $150 cab rides reduced to a maximum $65 Lyft ride, and participants had peace of mind knowing that transportation and costs were taken care of by the clinic. Clinical operations improved, significant cost savings were realized and participant experience was enhanced. Even new patients enrolled as a result of this added convenience. In March 2019, the clinic provided nearly 180 Lyft rides for its patients. As their organization continues to grow, they plan to expand this offering of Lyft rides for participants to their other sites.

Administrative Hurdles

Sites and their staff are critical to conducting successful studies. Coordinating travel for participants in clinical trials is an administrative burden that can often take site staff away from what they do best—research. They are experts in research, not travel. Therefore, they may not be prepared to properly address and support the travel needs of patients and caregivers. Sites typically operate during routine business hours, and are not staffed for around-the-clock travel needs. And with the management of many existing systems and databases to track information about patients in clinical trials, there is reluctance to learn and use more systems. Specialized solutions that are simple, easy and integrated can address a comprehensive array of travel and patient convenience matters through one singular login.

Sponsors and CROs

Sponsors and CROs have the goal of ensuring successful completion of clinical trials to attain new insights, treatments and medications that benefit patients in need. They want the top performing sites running clinical trials with the appropriate participants recruited and retained throughout the trial. While sponsors and CROs desire to empower sites with tools, they also aim to control costs and ensure financial visibility and predictability of the study budget.

Global and Local Customized Support

Clinical trials are conducted amongst the patient populations intended to benefit from new treatments or medications. In fact, patients can be recruited from around the world for a specific study. Travel arrangements and expense reimbursement for patients and caregivers therefore must be global in scope, yet, local in approach. Global support that is in market, with local language, time zones and an understanding of local customs at the forefront will bring tremendous benefit and comfort to participants, while removing the burden of travel arrangement from the site.

From the sponsor perspective, this translates to offering sites travel services and reimbursement programs in a seamless, stress-free experience that is aligned with global regulatory requirements.

> *75% of sites coordinate travel arrangements for patients (instead of having the patients make their own arrangements).*
>
> *- 2018 Society for Clinical Research Sites + Greenphire Research*

Guidance and Privacy

Privacy is an important consideration for sponsors/CROs as processes and systems must be compliant with global regulatory directives, such as the Health Insurance Portability and Accountability Act (HIPAA) in the United States or General Data Protection Regulation (GDPR) in Europe. These government regulations are designed to protect information and data collected and stored in medical records, anywhere that medical information is stored—doctor's offices, hospitals, research institutions and clinical trial study sites.

Prioritizing data security while facilitating travel and reimbursement are important to consider. Innovative solutions tailor made for clinical trials are dedicated to ensuring secure, blinded participant data. These technologies are not to be feared, but rather embraced, as their mission is in alignment with and supported by Ethics Committees and Institutional Review Boards—maintaining a focus on protecting the interests of the patients.

Financial Transparency

Predicting and tracking the cost of clinical trials is difficult. Often there is a lack of financial visibility due to numerous research programs included in a sponsor's budget that may vary by study or by country. Patient travel, accommodations and resourcing make up a significant portion of the study budget, requiring leadership approval. Introducing and standardizing technology solutions that allow for specialized travel service delivery while centralizing the critical data and transforming it into usable financial intelligence can enhance financial transparency, predictability and control, making it easier to track and forecast costs.

Opportunities to Evolve

To advance human health, it will be important to make clinical trials more accessible and effective for patients, caregivers and sites. Sponsors and CROs who introduce patient convenience initiatives such as travel arrangements and optimize workflows empower sites to focus on research, improving the experience for all stakeholders and driving desired outcomes.

Simplify Global Travel Operations Using ConneX™

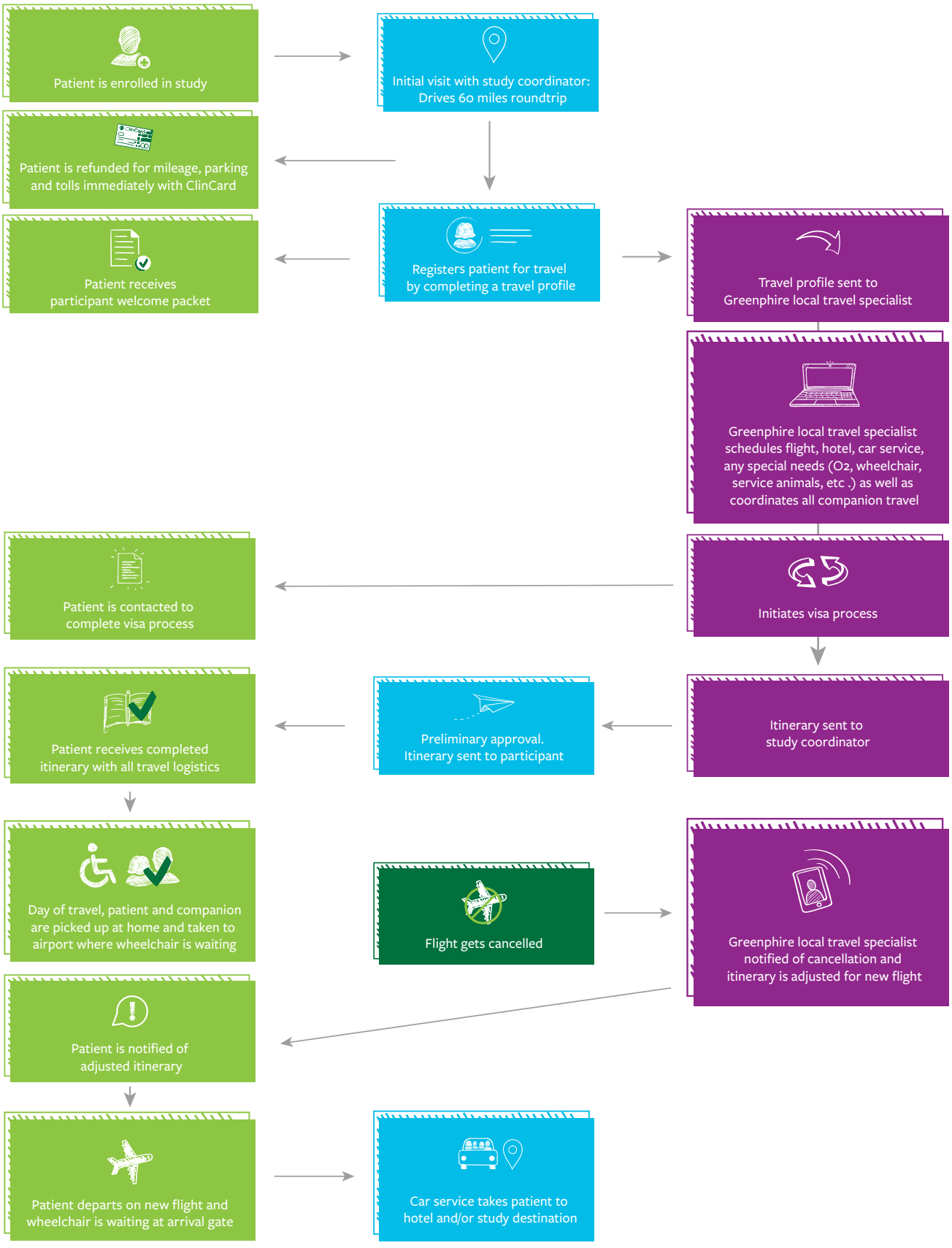
Greenphire understands the complexities of clinical trial travel, whether by protocol, therapeutic area or region. Greenphire's expert travel solution, ConneX, can be configured to meet the diverse needs of each participant, their caregiver, market and study, eliminating the logistical and financial limitations. From booking a ride, to full-service travel arrangements and hotel accomodations, ConneX provides peace of mind for patients and caregivers, sites and sponsors.

My patients love it, and words cannot express how happy my staff is with not having to worry about patients cancelling their appointments due to lack of transportation.

- Cheryl Zinar, Director of Clinical Research at MidLantic Urology LLC

A Patient Story

A Seamless Clinical Trial Travel Experience



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