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CLINICAL TRIAL-SPECIFIC TRAVEL PROGRAMS

AS A PATIENT RETENTION TOOL

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Placing an emphasis on patient retention is necessary for the success of a clinical trial. For many patients, participating in a trial is a major undertaking. Depending on the protocol requirements, study visits can be draining. There are a number of reasons why a patient may commit to participating in a trial only to drop out down the road. Conversely, there are a number of ways that sponsors can proactively try to prevent this from happening.

Patient retention can take many different forms, and in fact, it should be a multi-faceted endeavor. A sponsor cannot expect just one focused retention effort alone to improve patient dropout rates when the reasons why patients drop out vary. About 85% of clinical trials fail to retain enough patients, and those that do retain enough patients end up seeing a 30% patient dropout rate before study completion *(Forte)*. Here are some of the most common reasons why patients fail to see their studies through to the end:

- INCONVENIENT LOCATION
- FINANCIAL CONSTRAINTS
- PHYSICALLY UNABLE
- FEAR AND ANXIETY
- SCHEDULE CONFLICTS

Patient education, relationship-building efforts, and travel support are all helpful methods to combat these common dropout reasons. Perhaps the most impactful of these is travel support. About half of the reasons why patients drop out of clinical trials can be tied back to travel-related burdens, whether directly on the patient or on his or her caregiver. A patient who has to travel long distances to a study site or who has physical limitations that make traveling difficult will have a higher likelihood of dropping out of a trial, as will a patient who has to rely on caregivers to facilitate his or her travel needs.

The reliability of various transportation methods, travel expenses, and any physical obstacles that the patient may face can all make traveling to a clinical research site very unappealing. Trials may be recommended to patients frequently, but many may not even consider the opportunity if the study site is inconveniently located. Those who choose to enroll may eventually discontinue their study if the stress of traveling becomes too much. If patients were able to work with a travel vendor, the vendor would coordinate all of their travel for them. Patients wouldn't have to spend time looking for flights, airfare, and hotels, and they wouldn't have to pay out-of-pocket for those things either. Rather, a vendor would be able to make all necessary arrangements on the patient's behalf, enable an easy process for expense reimbursement, and provide the patient with an itinerary that would tell them exactly where to be and when. Travel vendors can also eliminate the issues of forgetting study appointments and scheduling conflicts by remaining in contact with patients and caregivers, reminding them of

study visit days and times, and working with them to find the most suitable options available. Clinical trial industry-specific travel vendors can make these services all the more valuable to sponsors and patients, as they will know the specificities of what is needed (as reads in a study protocol) better than a general vendor would.

INDUSTRY-SPECIFIC ADVANTAGES

Travel management vendors have entered into the clinical trial sphere specifically as a resource for sponsors, CROs, and research sites. Travel coordinators who specialize in the clinical trial sphere know how to communicate with patients, as well as how to convey SAEs or any other events to a site coordinator, if necessary. They also have a solid understanding of the protocol and visit schedule to ensure that no travel is booked outside of study visits. Coordinators who are well-versed in clinical trials can create a travel program that is IRB and EC compliant. The fact that these vendors create and manage the program takes the burden off the sponsor, from creating the travel program welcome packet to managing travel approvals. Most of these industry-specific vendors can also provide language for the ICF to ensure full compliance. Vendors can approve or deny travel requests based upon the guidelines that have been created and agreed upon with the study sponsor.

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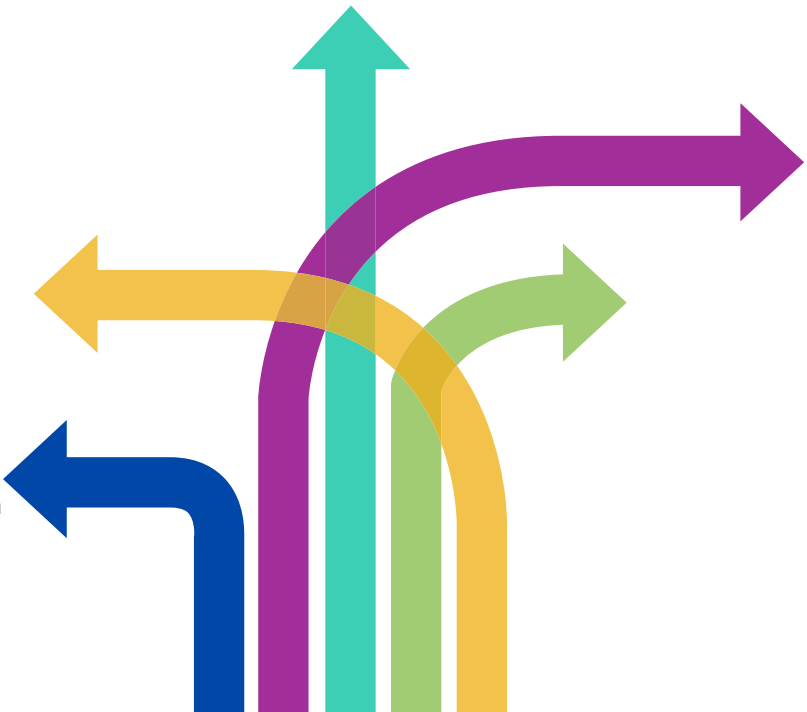
When providing a travel program for your clinical trial, it is important for the vendor to understand the distinction between what serves to assist the patient versus what could over-incentivize the patient. For example, providing the patient with a first-class airline ticket would be beyond what is allowed or approved within IRB guidelines. Instead of reaching out to the sponsor each time an instance like that arises, an industry-specific vendor would be able to preemptively approve or deny these requests among their team. In addition, being able to directly manage travel and reimbursement approvals removes any communication delays between the agent and sponsor, meaning patients won't miss out on a travel opportunity (a preferred rate flight or hotel) or have to wait longer for his or her funds. A clinical trial-specific travel vendor can handle these situations and ensure that no travel is missed and all payments are made on time.

Vendors that specialize in clinical trial travel also understand the importance of consistent communication with sponsors. They regularly provide reports and approvals to sponsors that are de-identified; patients are referred to with their study ID numbers, not a randomly assigned number. Many general travel vendors may not understand this process, and therefore present the risk of passing blinded information into the wrong hands.

THE PROCESS

Using a clinical trial industry-specific travel vendor for a study alleviates the stress on the patient, the study site, and the sponsor. Travel coordination is not a responsibility that any of those parties needs to take on. Patients should not be worrying about how they are going to get to their next appointment; they should be focused on adhering to the protocol. The site's main concern should be conducting study visits, not worrying about patient recruitment, and similarly, the sponsor should focus their attention on facilitating a seamless and productive trial.

Patients are required to travel at specific times in order to participate in a clinical study. Each study protocol will outline how often a patient is expected to visit a research site and for how long they need to be there. A good travel vendor will have a thorough understanding of a patient's visit schedule and will be able to easily anticipate when travel will be needed. Most often, these vendors will work with study site coordinators to confirm when patient visits are taking place. They will take the initiative to book travel for these visits with plenty of lead-time so that the worry is off both the patient and the site. A experienced travel management vendor will also remind patients directly to submit reimbursements for their travel expenses so that they are not spending out-of pocket funds.



A CASE STUDY

Here is an example of how a clinical trial-specific travel program functions in order to benefit patient retention rates:

A rare disease study took place over the course of three years at 75 study sites around the world. The study protocol outlined a 13-month commitment from the patients, with a rigorous visit schedule for the first three months of treatment. The sponsor for this study recognized that travel would be a significant barrier to overcome and so chose to utilize travel coordination and reimbursement services in an effort to combat anticipated dropout rates. Air travel, car transportation, and hotel stays were coordinated up front for all patients and caregivers, at no cost to the patient. Reimbursements for all out-of-pocket expenses incurred during the study visits were also processed. As a result of implementing these services, the patients and caregivers were able to attend all weekly study visits and the sponsor saw a 100% retention rate for patients utilizing travel services.

75% OF PATIENTS ENROLLED IN THE STUDY USED TRAVEL SERVICES

90% OF PATIENTS ENROLLED USED REIMBURSEMENT SERVICES

100% RETENTION RATE FOR PATIENT TRAVEL

REIMBURSEMENTS AND STIPENDS

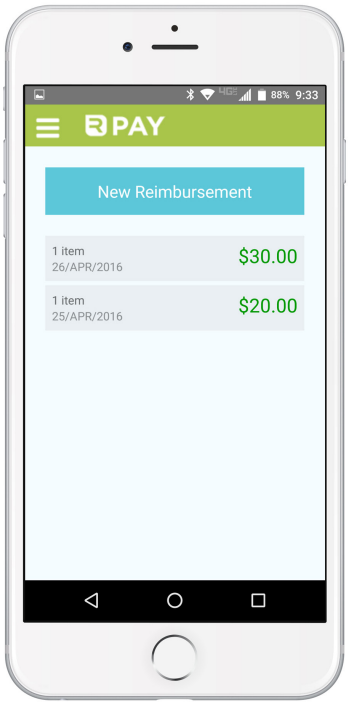
Sponsors find it very attractive when a travel vendor is able to facilitate patient reimbursement and stipend management on their behalf. Having one vendor manage travel, as well as reimbursements, makes the program more convenient and streamlined. It also leaves the sponsor with just one centralized point of contact for all of the services they are using for their study.

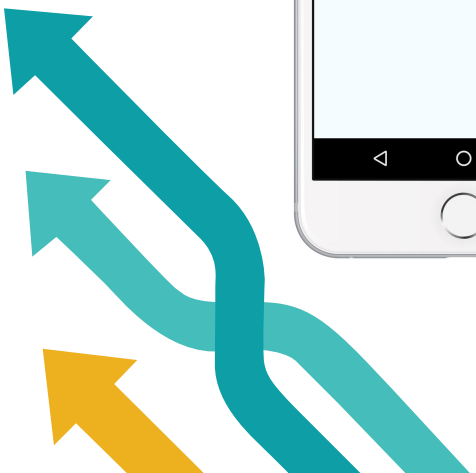
Compensating patients for their time participating in a study and reimbursing them for the funds they spend in order to participate can be overwhelming; it takes time to gather and review the reimbursement request, and additional time to have accounting specialists process a check for the patient. Hiring a travel management vendor reallocates this responsibility and helps ensure that the processes are more streamlined on the patients' end.

When the travel vendor can manage the process, it makes follow up after travel has taken place more efficient as the travel vendor will be familiar with patient schedules. In addition, payment can be processed a lot faster, ensuring that patients have those funds in time for the next study visit.

Reimbursements and stipends are often disbursed to a reloadable debit card. This makes it easy for the patient to receive his or her funds – it usually takes five minutes to process – and it also makes it easy for them to use the funds. A travel vendor can prepare reports for the sponsor for all stipend and reimbursement data on a per patient, per site, and per study basis. These reports are de-identified using the patient's study ID. This is an extremely helpful tool for sponsors as they work to make sure that they are running the most cost-effective studies possible.

MOBILE APP: There is a mobile app for everything in today's world, and clinical trials are no exception to this trend. Most travel vendors who facilitate financial transactions for patients host mobile apps on which patients can manage their reimbursements and stipends, as well as check their debit card balance. This is an incredibly attractive feature for a 21st century patient participating in a clinical trial, especially for those who are traveling. These apps allow patients to keep track of their spending, take photos of receipts, and store it all until the travel is completed and all expenses have been uploaded. With the click of one button they send their reimbursement request in real time, and once approved, are paid within a matter of minutes. Bank accounts can be linked and alerts can be set up to let patients know about fund transfers.





COUNTRY CUSTOMIZATION: Clinical trials around the world do not all look the same, and neither does global travel or financial reimbursements. Many out-of-country clinical trials are limited by ethics committees and some by access to transportation. Working with a clinical trial-specific travel management vendor will ensure that any given country's process is customized to that country's required specificities. For example, many medical facilities throughout Europe work with taxi companies for patient travel and have systems in place to pay them directly for transportation costs. Vendors can work with facilities on a site-by-site basis to determine the most appropriate means of patient transportation as well as the best route for reimbursement.

Patient retention can be a burdensome task for sponsors to take on. Travel vendors exist to alleviate this burden by offering hassle-free and reliable travel services to patients, as well as reimbursement and stipend management for those sponsors that want to offer it. Choosing to utilize a patient travel program that specializes exclusively in travel for clinical trials for your study will ultimately improve patient retention and result in successful clinical trial.

LEARN MORE ABOUT TRAVEL PROGRAMS FOR CLINICAL TRIALS BY CONTACTING ONE OF OUR SPECIALISTS TODAY.

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Sources:

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