White Paper

Clinical Trial Participant Payments: Navigating Global Complexity and Modern Studies

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Clinical trial management has only grown more intricate in recent years, driven by an increase of new modalities, study models, and regulatory expectations. For the sponsors overseeing these studies, one of the most challenging aspects of trial conduct is managing participant payments. Delivering site and investigator payments on schedule and in full is often difficult in itself; ensuring that participants are also compensated fairly and in a timely manner creates an added layer of complexity, particularly as sponsors work to scale their trials globally.

Compensation has been shown to act as a significant motivator for patients to enroll in clinical trials, as well as for remaining enrolled throughout the life of the study. According to Avoca's 360° assessment of the clinical trial industry, published in 2023, nearly 90 percent of patients surveyed cited payments as a key influence on their desire to participate in a clinical trial. However, just as many patients are often uncertain how participating in a clinical trial will impact their illness, many are likewise wary of whether they will be compensated for their efforts: only 28% of respondents from the same survey indicated that they believe compensation and pay will be given as expected in a clinical trial.

The methods most often employed for managing participant payments place most of the burden on trial teams. This not only creates an undue burden for sites but can also result in compounding issues as a sponsor works to scale its presence globally. Regulatory compliance, banking infrastructure, fraud prevention, data privacy, tax law — ultimately, the many shifting factors that accompany operating a global trial network are best served by truly global, comprehensive solutions, backed by expertise and supported by end-to-end technology platforms.

The status quo for participant payments: An overreliance on sites

There are two common approaches to managing participant payments for clinical trials. The first is to place the bulk of this responsibility on investigative sites, making them the primary point of contact for patients and entrusting them with managing every aspect of participant compensation. This is often achieved by building in additional fees to a site's Clinical Trial Agreement (CTA) budget and tasking clinical teams with meting out participant payments once they've received those funds from their payment provider. This setup is a cumbersome one, and, in an era where many clinical trial sites can afford to be selective around the sponsors they partner with, it can create a level of complexity some sites would rather avoid.

An overreliance on sites to perform participant payment management can:

- Result in additional steps/activities for trial teams, further complicating their already heavy workload and forcing them to perform work unrelated to patient care, or even to hire additional staff
- Lead to tracking payments and invoices that, submitted incorrectly, can cause compounding delays and disincentivize patients, particularly those who incur expenses for traveling to and from a clinical site
- Create complexity by tasking teams with navigating patient payments in ways that pass regulatory muster
- Create cash flow problems for sites that front delayed patient payments using their own funds (and leave those without access to additional cash with no means of readily paying participants)

The second approach frequently undertaken in managing participant payments also places much of the burden on investigator teams, with a technological buffer in the form of a third-party payment platform. In this scenario, sponsors identify a company — or, more frequently, companies — that have capabilities in the countries involved in a trial to act as vendor for sites, providing them a platform to manage payments but relegating the administrative work to site teams. This includes managing the form in which payments are disbursed (often a reloadable debit card) that trial teams must issue to patients and manage throughout the study.

Forcing sites to manage every aspect of these payments — from replacing lost cards to safeguarding payments and freezing lost or stolen cards — means that these solutions often do little to alleviate the burden of payment management for trial sites. This approach is also one-size-fits-all, and participants are given no other options for how they wish to receive payments, which may disincentivize some participants, particularly if issues with payments occur. In a clinical trial landscape set on simplifying the study experience for both patients and sites, these approaches are far from optimal and can run up against significant roadblocks in certain countries or regions where more calibrated approaches are needed to meet legal and regulatory requirements.

Managing global complexity: A spotlight on country-level challenges

While there are a handful of countries where conducting clinical research is made virtually impossible by law, political climate, or medical access, there are many others that are well-positioned to add value to a study but require additional expertise or support to incorporate into a trial or program. These locations are often home to diverse patient populations, premier medical institutions, and integral infrastructure, but intricacies in broader laws or regulatory standards can make them tougher to navigate for sponsors without the right support.

Here are a few examples of some of the stumbling blocks sponsors can encounter around the globe:

China: For those struggling with recruitment, places like China can represent a unique opportunity with its vast population of treatment-naïve patients, many of whom suffer from indications Western countries are eager to access for their trials. Conducting trials in China can be equally attractive for its relative cost effectiveness — direct costs for trials in China are estimated to be approximately 30 percent lower than those in Western countries. Moreover, recent regulatory reforms have streamlined approvals and improved clinical trial infrastructure, together bolstering China's status as an emerging clinical trial leader.

So, what are the limitations to conducting a study in the world's most populous nation? Here are a few:

Regulatory oversight and ethical considerations: China boasts a stringent regulatory environment, and its National Medical Products Administration (NMPA) requires detailed documentation and lengthy approval processes, which can significantly delay payments

Anti-bribery laws and data privacy: China's anti-bribery laws are likewise rigorous and require careful scrutiny around the structure and format of participant payments to skirt legal issues. Another big potential complication centers on the nation's data privacy laws, which impose strict rules on how personal data, including payment information, can be handled, serving to complicate the logistics of participant payments

Limited payment structures and cybersecurity concerns: While China's digital payment systems are advanced, it is often difficult to integrate them with international clinical trial payment solutions. Additionally, China's cybersecurity laws are notoriously strict, necessitating significant expertise to navigate this added complexity and support robust data storage solutions

Brazil: Brazil is another country that offers sponsors a great value proposition — its diverse patient population and representative disease prevalence, coupled with a comparatively high enrollment and retention rate for clinical trials, make it an attractive option on the global stage. However, challenges related to regulation, law, and digital and fiscal infrastructure can be hard to surmount without the right expertise.

These include:

Complex approvals: Historically, Brazil has required two levels of approval for clinical trials — one from local ethics committees and another from the National Research Ethics Commission (CONEP). While the government has attempted to address this complexity through recent legislation, the transition will still likely require significant local expertise to surmount lingering challenges

Compensation and post-trial access: New laws around participant compensation that curtail compensation or incentivization outside of Phase I trials require careful navigation on the part of sponsors. Additionally, Brazilian law mandates that clinical trial participants have access to investigational medications post-trial until they become available through regulatory approval

Participant payments and data privacy: Though its banking systems are relatively advanced, integrating international payment systems for trials in Brazil can be difficult with some local infrastructures. Other technological challenges related to data privacy likewise necessitate stringent data handling, including for payment information

Bulgaria: A key advantage of conducting clinical trials in Bulgaria is its focus on enabling efficient patient recruitment; moreover, its centralized healthcare system and large, specialized medical centers serve to further streamline study conduct. It also boasts lower per-patient costs than many Western countries, cementing it as a valuable resource for global clinical trial programs.

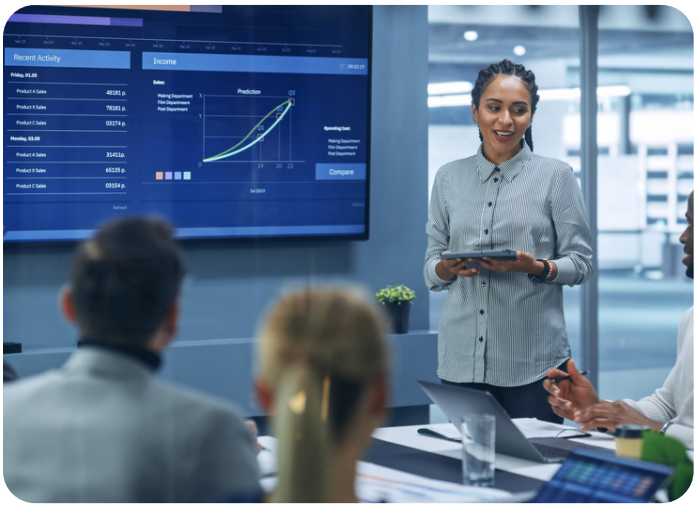
Yet as with many emerging clinical research destinations, there remain stumbling blocks to participant payments.

These include:

Complex approvals and ethical review: While Bulgaria follows EU Clinical Trials Regulation No. 536/2014, this harmonization requires detailed documentation and approval from both the Bulgarian Drug Agency (BDA) and the central ethics committee, which can delay payments. Ethical review in Bulgaria is also rigorous, requiring thorough assessments from its ethics committee and adding time to the approval process

Data privacy and financial regulations: Bulgaria adheres to the EU General Data Protection Regulation (GDPR), which imposes strict requirements on handling personal data such as payment information. Its financial system is also highly regulated to prevent money laundering and fraud, resulting in the potential for additional scrutiny for compensating participants

System integration and cybersecurity: Bulgaria's banking system is also advanced and well-regulated, but, as with Brazil and other countries, integrating international payment systems with local infrastructure can be challenging. Bulgaria's adherence to EU cybersecurity laws is likewise stringent, necessitating a focus on data protection



The solutions to these hurdles — relationship-building with regulators, adequate documentation of payment practices, robust cybersecurity protocols, local partnerships with medical providers, training, and other approaches — require a comprehensive and global payment platform with regional reach and a niche understanding of country-specific idiosyncrasies in law and regulation.

The value of global reach for clinical research

Ultimately, when it comes to participant payments, many sponsors may not realize the value that a global solution — one that removes the burden of payments from sites and is able to assist in even the most challenging regions — can have for a clinical research pipeline. As participants and investigators alike come to expect more from the technologies supporting trials, and as other elements of trial conduct, such as electronic data capture (EDC) platforms, evolve to prioritize user experience, sponsors that can offer truly global solutions will be key to both improving patient retention and attracting the best clinical trial sites in the world.

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