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JUGGLING RECRUITMENT RISKS IN CLINICAL TRIALS

BY DAN BRETTLER

Successfully executing a clinical trial requires juggling the complexities associated with the clinical process along with developing sufficient incentives to promote enrollment.

For many sponsors, removing barriers to participation is essential not only to improve the chances of reaching enrollment targets but to assure that both the science behind the protocol and patient safety are balanced to achieve the sponsor's goals. Often balancing science with a successful recruiting effort while ensuring the balance sheet is protected from exposures which might not be otherwise protected under traditional negligence-based clinical trials insurance policies factor into the success or failure of the recruiting effort.

Regulators are trying to balance participant safety with the desire to avoid putting bureaucratic obstructions in the path of life-saving innovations. Still, regulatory variations from country to country and differing legal frameworks on issues such as advertising, recruiting, reimbursements, data privacy and human subject protections are making it more challenging to recruit subjects and balance inducements with safety as sponsors draft clinical trial agreements and informed consent documents.

While sponsors must balance a multitude of issues in order to organize an investigation, address requirements for subjects and investigators and ultimately create a comprehensive protocol and consent process, finding suitable participants often means going far and wide since the pool of subjects may be limited and/or affected by numerous variables such as use of existing medications, other health conditions, involvement in other studies and even geography.

This is forcing many clinical trial sponsors to ask participants to travel across state or international lines. However, this opens up a new set of risks that must be addressed.

CLINICAL TRIAL SUBJECT TRAVEL RISKS – A GROWING CONCERN

The exposures faced by subjects who may need to travel, sometimes between countries, to participate in a study are often overlooked. While compensation is increasingly used to recruit subjects, it has only been until recently that the consent form has addressed travel risks and expenses. Increasingly, sponsors are including provisions in their consent documents that obligate them to address injuries or illnesses for subjects and companions/caregivers that might arise during the journey to or from the trial site.

Unfortunately, typical clinical trial insurance may not respond to that obligation, creating potentially significant financial consequences for the sponsor in the event that an accident or illness arises during the trip.

A careful review of clinical trial provisions is imperative to establish whether medical payments might indemnify subjects who are injured in the process of traveling to or from a trial site. Such insurance may only indemnify for an event arising out of a sponsor's negligence, as a result of contractual obligations. It may also only apply geographically to limit the scope and substance of any coverage available in the clinical trial policy.

Typically, such insurance is limited to a trial site and the clinical activities that the subject may be exposed to. In some cases, medical payments insurance may be included to assure that treatment is prompt and addresses immediate injuries or adverse reactions by the patient.

PAIRING CLINICAL TRIAL WITH TRAVEL AND ACCIDENT INSURANCE

For injury or harm outside of the trial or trial site, including reimbursement for medical expenses or other costs, clinical trial insurance often fails to address this risk. In the event it does, it is limited to the indemnification of certain medical expenses. Coverage may be further limited by deductibles or co-participation clauses. Germany is one of the few countries in which insurance provisions beyond the trial site are customarily required by an ethics committee, but only for travel within the country. Of course, depending on the nature of the investigation, it may be necessary to recruit subjects across Europe or beyond.

One solution offered by certain underwriters with expertise in the life sciences industry is to pair clinical trial insurance with travel and accident products.

Travel and accident insurance often include coverage for specified amounts due to loss of life, physical disability, including certain illnesses, or impairments. Coverage for subjects of a clinical trial may also include those accompanying them such as a parent or caregiver. Coverage may specify a limit of insurance for accidental death and dismemberment, for accident medical expense and for medical evacuation or repatriation expense. Typically, the policy will specify a principal sum for each section subject to a maximum benefit amount. In many cases, insurers will automatically aggregate maximum benefits between two and 10 times. Depending on the principal sum insured, it is important to assure that aggregate limits are provided in multiples sufficient to address the total participants involved in the study. There are some jurisdictional limitations that limit eligibility however some insurers may close the gap by modifying medical payments provisions. In addition, some insurers offer a variety of travel assistance services.

A BROKER'S VALUE

It is important to retain an insurance broker knowledgeable of your industry and with deep expertise on the exposures, including the impact of your commitments or those of your contractors to compensate those subjects recruited to participate in a sponsored clinical trial.

Significant relationships with specializing life science underwriters are essential to protect your balance sheet.

These insurance professionals can assure that coverage is in place in compulsory jurisdictions worldwide and that you have adequate limits of insurance and coverage across the globe. Combined with a strong claims-handling pedigree, working with such professionals may protect your firm's reputation, directors and officers and critical assets.

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