CHUBB

Trial and Cure – the life-saving role of clinical trial insurance

Globally the number of clinical trials has been on the increase, indicative of both the growing innovation in the pharmaceutical and healthcare industries, and an equally increasing burden of disease needing new medical cures and treatment. Clinical trials are crucial to determine the safety and efficacy of pharmaceutical and biological products as well as medical devices, before they can be prescribed or sold. Although years of research goes into reducing the risk that such trials represent to their human subjects before tests are conducted, there is an inherent risk in every clinical trial that demands bespoke clinical trial insurance to protect the trial owner and participants in their pursuit of life changing cures and technologies.

"South Africa is no stranger to clinical trials, and is credited with some of the most ground-breaking and globally significant work done in HIV and TB clinical trials," says Alexandra Schudel, Head of Financial Lines and Casualty at Chubb Insurance SA. With the high prevalence of such diseases in our country and neighbours, many such trials are conducted by international sponsors in South Africa.

"There are inherent risks in medical research, more so when your test subjects and trial participants are people. Specialist clinical trial insurance provides vital financial protection for those conducting clinical trials in addition to compensation for trial participants who could suffer harm. The cover is provided based on the number of participants and the extent and level of risk of the clinical trial, with the inception of cover on the first date of clinical testing and for the duration of the trial," adds Alexandra.

When things go (badly) wrong

"While cases of early-stage clinical trials going badly wrong are rare, they are not unheard of, and can have unexpected and devastating consequences for volunteers," says Kevin Stokes, Director of Highgrove Financial Services, a specialist insurance brokerage. "Well-known trial failures around the world in the last decade have led to significant and permanent injuries to trial participants and in some instances death, and were followed by hefty liability claims in addition to severe reputational damage to the trial owners," adds Kevin.

Clinical Trials in South Africa

In South Africa, all clinical trials of both non-registered medicinal substances and new indications of registered medicinal substances must be reviewed by the Medicines Control Council (MCC). The MCC has a statutory obligation to ensure that the drugs available in the country fulfill the necessary requirements for safety, quality and efficacy. As a result, it is a requirement in South Africa that all participants in clinical trials have comprehensive insurance cover in place for injury and damage purchased by the owner. The MCC also has the authority to shut down a clinical trial if there is a serious breach of good clinical practice.

What about informed consent?

While all participants in a clinical trial must provide their informed consent, litigators will often pursue arguments along the lines of the complexity of information and whether a reasonable person could be expected to fully understand such information; a lack of adequate explanation; a lack of full disclosure of potential adverse effects; or simply being pressurised to go through with the process. Informed consent could be voided in these instances and negligence can be alleged in order to pursue an action for the injuries.

"Even where there is no failure in informed consent, there are often no-fault compensation guidelines that will allow compensation to be paid to patients where there has been a significant and life-changing injury," says Alexandra Schudel, Chubb.

"There is general consensus that clinical trial subjects are doing something positive for society, so when a volunteer is significantly injured, there is a willingness to compensate them even where there is no apparent fault or negligence. There has been a high adoption of no-fault compensation guidelines in clinical trials insurance, recognising the significant contribution of trial volunteers in the advancement of medical science and research."

The need for clinical trial insurance

Ultimately, until you commence first-in-human trials, there is no way to know exactly what a treatment can do. While you can mitigate the risks, you can never remove it completely. There is always the chance that a patient can suffer an adverse reaction, no matter how much research has been carried out.

"While policy wordings do not tend to differ widely between insurers, each will have its own and specific approach. The focus should always be on the sponsor's needs and the insurer's ability to understand the risks. Clinical trials insurance focuses on protecting the participant, which in turn reduces the risks to the sponsor's reputation. Having a global footprint is crucial as many trials are conducted across borders and have differing jurisdictional laws with regards to trials. Local laws may also require that insurance is underwritten by an insurer that is licensed to issue policies locally, but not all insurers may be able to do this. This puts claims payments at risk," says Alexandra.

If something goes wrong in a clinical trial, it can be costly for all involved and have particularly devastating results for the wellbeing of the trial participant. A participant suffering life-changing complications or death carries huge reputational and financial repercussions for the trial owner. Clinical trial insurance provides a vital safety net to protect the best interests of the trial participants and the inherent reputational and financial risks that come with an uncertain outcome.

Get in touch

Additional information can be found at:
www.chubb.com/za