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 Finanical 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...
The life saving role of clinical trials insurance

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.

“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.”

Get in touch

For more information on how Chubb can provide a safety net to protect clinical trial participants and sponsors, contact Alexandra Schudel at alexandra.schudel@chubb.com