CLINICAL TRIALS INSURANCE

howden
specialist insurance brokers

“GIVEN THE HIGH RISK NATURE OF CONDUCTING CLINICAL TRIALS COUPLED WITH THE POTENTIAL LEGAL REPERCUSSIONS OF SUCH A TRIAL GOING WRONG, ENSURING THAT YOUR CLINICAL TRIAL INSURANCE IS NOT ONLY COMPREHENSIVE BUT MEETS THE SPECIFIC REGULATORY REQUIREMENTS OF THAT PARTICULAR COUNTRY IS NOT JUST IMPORTANT – IT IS ESSENTIAL.”

Tomer Karni

Director, Life Science, Howden.

THE RISKS

The clinical trial is a critical phase in the validation of both the effectiveness and safety of any drug or medical device. Yet no matter how intensive the pre-trial procedures undertaken, human testing is extremely high risk, and the potential repercussions of a trial going wrong can be devastating. Legislation worldwide governing clinical trials is aimed at safeguarding the health and well-being of trial participants. Unsurprisingly, this leaves those involved in conducting such trials open to litigation.

Failure to comply with the regulatory structures governing trial protocol, informed consent procedures and Helsinki / IRB approval processes leaves parties to the trial exposed to legal action from participants. Furthermore, recent legislative developments, such as the Medicines for Human Use (Clinical Trials) Regulations 2004 in the EU, have served to expand the liability net further to encompass both sponsors and investigators. Medical practitioners, contractors, consultants, contract research organisations, the Ethics committees, or indeed any other entity operating within the scope of their trial duties, are all at severe risk of legal action should anything go wrong.

THE SOLUTION

Clinical Trial insurance provides an essential protective mechanism for any organisation involved in the conduct of clinical trials. Regulatory bodies around the world demand a clinical trial sponsor to protect the trial's participators. While the details of such requirements can differ depending on the territory, the fact that it is mandatory does not.

THE COVER

The regulatory environment governing clinical trials varies from region to region. It is therefore paramount that clinical trial sponsors select the correct Clinical Trial insurance cover. At Howden, our knowledge and expertise is the foundation to ensuring that your cover meets the specific requirements of your particular region. Our services include the provision of:

- Regulatory wording, limits of indemnity and deductibles
- Top-up limits of indemnity
- Single trial, multi-year policies
- Annual multi-trial policies.

In certain instances, the cover may be required to span multiple territories. Once again, our expertise comes to the fore in ensuring that the policy is tailored to the precise coverage requirements of each particular territory.

OUR CLAIMS TEAM

Howden understands that the role of a good broker is much more than simply designing the right insurance product and placing it at a keen price. We also offer our clients an in-house claims management team, experienced in handling large claims. While no one wants to envisage a law suit which could result in a claim, with Howden's experts on your team you can be sure of having the very best people working to get your claim paid.

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