



CLINICAL TRIALS AND TRIBULATIONS



Insurance for your reputation



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Undertaking clinical trials is a time consuming and costly exercise for businesses as well as being a regulatory minefield. Add to that, the responsibility for arranging appropriate insurance cover and the issue can become more complex.

Compensation and Legal Liability

It is often wrongly assumed that asking participants in clinical trials to sign a Consent Form absolves all parties of liability for injury whilst involved in the study. However, it is imperative to recognise how a Clinical Trial policy is structured to fully appreciate that this may not be the case.

Clearly, it is for the greater good that individuals should volunteer for studies in the knowledge that should something go wrong they will be suitably compensated.

To that end, a Clinical Trials policy has two constituent parts: a compensatory aspect where no cause has to be proven (ie. no proven negligence on the part of those running the trial), simply that whilst participating in the trial that the volunteer has suffered some form of injury. There are compensation guidelines for such instances.

The policy also provides for legal liability. In such circumstances the injured party may not feel that the compensatory aspect is suitable recompense for their injuries and may pursue a legal action against those running the study.

The mere fact that someone has signed a Consent Form is no

defence in itself. Those running the trial must be able to demonstrate that the process and potential downsides were fully explained to them and that they have exercised a suitable standard of care throughout all facets of the trial.

'Run Off' Liability

Care should be taken in relation to the scope of cover afforded by any clinical trial insurance.

Policies are typically arranged on a single or multiple trial basis for an annual policy period irrespective of the duration of the trial. Clinical trial insurance is arranged on a 'claims made' basis which means that the policy is in force when a claim is made is the one that would respond to the claim. As a result, it is important to make adequate provision for any potential 'run off' liability once a trial study has concluded. Clearly, what this period should be is often dictated by the nature of the trial ie. a trial involving a permanent implantable device is likely to require a longer 'run off' period. This can either be catered for by continuing to renew the policy on an annual basis or paying an additional premium for a set 'extended reporting period'.

Overseas Trials

Where recruitment of volunteers is difficult given the nature of the particular study it is sometimes necessary to undertake studies in a number of countries. In doing so, businesses are often caught out by the fact that in certain jurisdictions it is a local requirement that an

'admitted' policy (a policy issued in that territory) is put in place to cover the trial work in that country.

What this means in practice is that a business may need to arrange multiple policies with separate limits in different countries to cater for what is in essence the same trial work. This is likely to be dictated by local requirements in terms of policy wording and limits,

In summary, there are some fundamental pitfalls in arranging Clinical Trials Insurance and it is vital that you involve your insurance adviser at an early stage in the process, to establish the requirements and options available.

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