

CLIENT ADVISER

CLINICAL TRIAL INSURANCE – IS YOUR INSURANCE FIT FOR PURPOSE?

The shocking consequences of the recent failure of the BIA 10-2474 clinical trial undertaken by Biotrial on behalf of BIAL at the University Hospital of Rennes in France are a salutary reminder of the risks which are present within the clinical trials regime. In this case, at the time of writing, there has been one death and five further hospitalisations.

Despite the extreme and constant attention given to the care and safety of volunteer trial subjects taken by sponsors, contract research organisations, site management organisations, institutional review boards, ethics committees, and the like, whilst, very rare, injury and death can still manifest.

This adviser raises the key issues to consider when arranging clinical trials liability insurance, particularly when taking place outside of the UK.

Globally, in almost all countries which host trials, the local ethics committee or regulator will expect or demand a minimum level of insurance to be in place before the trial can commence or continue. This is to ensure that volunteers have adequate financial protection for any medical and treatment costs, and to provide appropriate compensation in the event of death or injury arising from an incident caused from the trial activity.

Unlike within the UK, where a single annual generic certificate can suffice for all of a sponsor's trials for a year, insurance requirements differ widely in other countries. Regulators are scrupulous about compliance with the detail before the approval of clinical trial insurance certification. Insured limits and extended discovery periods can differ greatly. Policies may be combined with public and/or products liability coverage in some countries, but must be stand-alone, trial-specific in others. The Named Insured is usually the sponsor but also may demand the contract research organisation, trial managers, investigators, and/or other parties, depending upon the host country. Some covers are governed by legal liability, whereas others are determined on a no-fault basis.

Local language certification is frequently mandated and local legislation and regulations may change from time to time.

What are the key issues to consider when arranging clinical trials liability insurance?

- Awareness – Sponsors must make sure they are aware of local country requirements prior to conducting the trial, as the obligations of the sponsor in some territories are more onerous than others.
- Information – Country specific pre-requisites for certificates must be provided.
- Timeliness – Policies and certificates must be provided in time to meet the sponsor's submission timelines in order to obtain ethics committee approval well in advance of a trial's intended inception date – "just in time" is not recommended.
- Accuracy – Cover must be compliant with local legislation and/or regulation to ensure compensation is granted in accordance with jurisdiction requirements. This is particularly important when multi-country trials are contemplated.
- Capability – Insurers need sufficient claims expertise and local capability to ensure claims notifications are dealt with in a quick and expedient manner.
- Experience – Your broker should be well versed and experienced in clinical trials insurance requirements across the globe to give you professional advice and support, particularly when you expand trials internationally.

Sponsors are encouraged to review their existing insurance arrangements and satisfy themselves that their clinical trials risks are adequately covered and that all documentation is compliant with current local ethics committee and country regulatory requirements.

MARSH'S CLINICAL TRIALS CENTRE OF EXCELLENCE

Marsh's Clinical Trials Centre of Excellence serves a wide range of clients across the globe with insurance placements and administration. Our programmes range from single trial policies to all embracing annual covers for global pharmaceutical and healthcare organisations.

Our clients have access to our global trials guidance tool explaining the regulatory and practical requirements of clinical trials insurance per country. Our strong established relationships with all insurers enable us to identify the optimum solution for each enquiry.

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If you have any enquiries regarding clinical trials liability insurance, please contact your local Marsh representative or:

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