

CLINICAL TRIALS INSURANCE

Why Clinical Trials Insurance Policy?

Clinical Trials are vital and important for finding new, better & more effective Medicine. Whenever any new medicine/therapy is to be launched, it must first be tested in lab on animal or human cell. If the results are encouraging than it is tested on human being. There is commercial advantage to the firm that produce the first approved drug for a disease. That being the position there is dramatic increase of clinical Trials. India has now become a favourable destination for clinical Trials because of availability of expertise, infrastructure, availability of patient /research subject and low cost. In any case, in today's litigious society, parties are sued regardless of who or what caused injury or death.

This being the ground reality, insurance must form part of any risk management philosophy of the company interested in clinical time. As a part of any clinical trial, therefore, need proper monitoring and proper insurance cover. Even then in spite of all precautions being there, liability will arise because of the human element and other factor and hence need insurance.

Scope of Cover

The Clinical Trials Insurance policy covers:

- Legal liability arising out of clinical trial or healthy volunteer study, resulting in Bodily Injury of the Research Subject (person participating in the clinical trial or healthy volunteer study)
- All reasonable Legal Costs including defence cost as per the Conditions of Compensation of the Policy

Some of the other highlights of the Policy are:

- A broad definition of Insured under the Policy that may include, (i) directors or partners insured person or company; (ii) any employee of the insured person or company (excluding Medical Persons); (iii) any past employee who acted for the insured person or company; (iv) Medical Persons who are employees of the insured person or company; (v) any sub-contractor, doctor, consultant, physician, hospital or contract research organization or nurse who performs work for the insured person or company in respect of a Trial; (vi) any Ethics Committee or its members that has approved a Trial;
- Cover for Research Subject in case of death/injury. Research Subject is broadly defined in the Policy and also extended to mean dependants, heirs, executors, administrators, and legal representatives.
- Provision to pay compensation as per the Conditions of Compensation in the Policy
- Cover to Ethics Committee (For Manslaughter Defence Costs)
- Cover can be granted to cover medical expenses as an extension on the Policy.

Exclusions

The following are excluded under the Policy and are not covered:

- War and invasion

- Radioactivity and Nuclear
- Occurrence prior to the Retroactive Date
- Claims arising out of Occurrence the circumstances of which insured had prior knowledge.
- Failure of Product/Drug
- Failure to cure or alleviate.
- Terrorism
- Asbestos
- Mould
- Financial Loss not consequent upon Bodily Injury
- Costs incurred on repair or replacement of any drug or product or any part thereof
- Product or drug recall
- Compensation to Research Subjects for placebo's failure to provide therapeutic benefit or in relation to natural progression of an underlying disease.
- Claims arising from the production, sale and provision of certain drugs or products.