

### SER CLINICAL TRIAL INSURANCE

New drugs are constantly attracting media attention because of their possible side effects. In the worst case, drugs have had to be completely withdrawn from the market. The company concerned suffers huge financial loss and at least in the short term, damage to its reputation.

Medicines for human use are discovered by the research and development department of pharmaceuticals manufacturers and prior to marketing of these of product trials are conducted. The object of conducting such trials is to generate adequate information on the efficacy of the and ministered medicines and their safety.

#### What is Clinical Trial?

A Clinical trial is a potential treatment on a human being to watch the success of the medical application and whether they could be put to wider use for the general population as a whole.

It is possible that in conducting clinical trials there are uncertainties and imponderables, leading to unpleasant, serious or even life endangering side effects, the treatment may be ineffective in certain body conditions of the individuals. The treatment may be a drug or a medical device or a surgical or physical procedure, a therapy or an intervention.

When a particular clinical trial conducted on a selected human being is ineffective and poses new medical problems such as unanticipated disablements including loss of life, there may arise a legal liability on the research institute and drug companies who have undertaken the clinical trial. The affected person and or their legal heir may proceed against the institution claiming compensation and it is a potential liability against which specific insurance is required.

#### Clinical Trial Insurance

This demands introduction of new types of insurance policies providing a suitable cover, encompassing the risk elements of Human Clinical Trials. Arising out of this requirement i.e. legal liability for clinical trials we have framed Clinical Trial Liabilities Insurance Policy offering protection to the company engaged in the trial.

The legal liability, by operation of law is an event upon which the obligation of the insurer to indemnify the insured depending upon the happening of the occurrence insured against. There is a distinction between the products liability insurance which is for a finished product where as, a clinical trial liability would be a liability of unproven and unregulated product in its testing stages.

#### Policy Coverage's and General Exclusions

The Company will indemnify the Insured in respect of clinical trial for each and every claim where legal liability is established and an aggregate limit for all claims arising out of anyone events. It is requirement that then person making a claim on the insured (company) for any bodily injury, sickness or disease or a different medical condition should have been subjected to the clinical trial conducted by the organization-Insured.

The damage payable could be a monetary compensation or a statutory damage but does not include punitive or exemplary damages, fine, penalties or costs of compliance with equitable reliefs. The costs of defending a law suit for an admissible claim is payable by us and such costs are included in the limit of liability.

The Covers offered under the respective sections are as follows:

#### Section 1: Settlement with Mediation

Indemnifies the Insured, for all sums which the Insured shall pay to a research subject as a result of a settlement agreement reached between the research subject and the Insured, in the event of a claim by the research subject against the insured arising out of the research subject's participation in a trial commencing within the Policy Period.

#### Section 2: Legal Liability

Indemnifies the Insured, for all sums including legal costs which the Insured shall be legally liable to pay as damages and compensation awarded by a court for property damage as well as bodily injury, personal injury and advertising injury caused to a research subject by the research subject's participation in a trial commencing within the Policy Period.

#### Section 3: Medical payments Coverage

The Company will pay for medical payments in respect of each research subject who sustains bodily injury arising out of their participation in a trial when such injury was incurred during the Trial Period and reported to the Company within one year from the date of sustaining the bodily injury. This section excludes medical payments for bodily injury to any person taking part in athletic pursuits concurrently with a trial.

Following are some of the exclusions under the policy:

- No compensation for pain and suffering
- Any claim arising out of any trial commencing prior to the Retroactive Date
- No insurance cover for medical malpractice
- No insurance cover for inefficacy of the clinical test
- Punitive or exemplary damages
- Injury sustained by any employee arising out of and in the course of their employment or engagement by the Insured
- No insurance cover for injuries to health and deterioration of health for already existing injuries to health that would have also occurred or continued to exist if the insured had not participated in the clinical test
- Any claim arising out of or in any way connected with any Trial undertaken without the approval of Human research ethics committee

It is a requirement that the insured institution shall conform and observe good Clinical practices for clinical Research prescribed for conducting clinical trials.

The clinical trial to be conducted is restricted to living human beings and would not include animals and resultant claims from owners of such pet animals.

#### Who can buy this cover?

- Pharmaceutical Companies
- Clinical Research Organization
- Hospitals, Medical Institutes and Universities
- Sponsors of the Trial
- Individual professionals

#### Service and Strength

HDFC ERGO can offer one trial one policy and also multiple trial one policy depending upon the requirement. Coverage can also be provided upto the duration of the trial.

At HDFC ERGO General Insurance Company Ltd, we deliver more than just insurance products. We support our customers through our renowned services, extensive network of claims adjusters and financial strength. Our loss control professionals are experienced in making risk assessments and proposing practical remediation to help mitigate or prevent losses. Our claim service is legendary in the industry. Should a loss occur, our exceptional claim service is available anytime/anywhere through our Customer Service number or via our website.