

SER Clinical Trial Insurance - Prospectus

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 In the worst case, drugs have had to be completely withdrawn from the market.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 trail 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

CANCELLATION

The Insured can cancel the policy at any time during the policy term, by informing the Company. The Company can cancel the policy only on the grounds of established fraud, by giving minimum notice of 7 days to the Insured.

The Company shall refund proportion premium for unexpired policy period subject to no claim(s) made during the policy period.

THIS PROSPECTUS

This prospectus gives information only. This is not an insurance contract. Each insurance cover is subject to terms and conditions, which You can read in the SER Clinical Trial Insurance document. You must read the policy document to know the insurance cover fully. You can get a copy of the SER Clinical Trial Insurance from Our branch or from Our website: www.hdfcergo.com For any legal interpretation, policy document will hold.

GRIEVANCE REDRESSAL PROCEDURE:

If You have a grievance about any matter relating to the Policy, or Our decision on any matter, or the claim, You can address Your grievance as follows:

Our Grievance Redressal Officer

If you have a grievance that you wish us to redress, you may contact us with the details of your grievance through:

- Contact us- 022 6158 2020/ 022 6234 6234
- Emails - grievance@hdfcergo.com

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- Contact Details for Senior Citizens: 022 6242 6226 | Email ID: seniorcitizen@hdfcergo.com Designated Grievance Officer in each branch.
- Company Website - www.hdfcergo.com
- Courier - Any of our Branch office or corporate office

You may also approach the Complaint & Grievance (C&G) Redressal Cell at any of our branches with the details of your grievance during our working hours from Monday to Friday.

If you are not satisfied with our redressal of your grievance through one of the above methods, you may contact our Head of Customer Service at

**The Complaint & Grievance Redressal Cell,
HDFC ERGO General Insurance The Company Ltd
D-301, 3rd Floor, Eastern Business District (Magnet Mall),
LBS Marg, Bhandup (West),
Mumbai – 400078, Maharashtra**

In case you are not satisfied with the response / resolution given / offered by the C&G cell, then you can write to the Chief Grievance Officer of the Company at the following address

**To the Chief Grievance Officer
HDFC ERGO General Insurance The Company Limited
D-301, 3rd Floor, Eastern Business District (Magnet Mall),
LBS Marg, Bhandup (West),
Mumbai - 400078, Maharashtra
e-mail: cgo@hdfcergo.com**

Grievance may also be lodged at IRDAI Integrated Grievance Management System- <https://bimabharosa.irdai.gov.in>

You may also approach the nearest Insurance Ombudsman for resolution, if your grievance is not redressed by the Company. The contact details of Ombudsman offices are below if your grievance pertains to:

- Insurance claim that has been rejected or dispute of a claim on legal construction of the policy
- Delay in settlement of claim
- Dispute with regard to premium
- Non-receipt of your insurance document

You may also refer Our website www.hdfcergo.com <https://www.hdfcergo.com/customer-voice/grievances> for detailed grievance redressal procedure.

ABOUT OUR COMPANY

Name of the company – HDFC ERGO General Insurance Company Limited (IRDAI Reg No 146)

Registered & Corporate Office: 6th Floor, Leela Business Park, Andheri-Kurla Road, Andheri (East), Mumbai – 400 059.

Website – www.hdfcergo.com

Contact number – 022 - 62346234

Email – care@hdfcergo.com

INSURANCE ACT 1938 SECTION 41- Prohibition of Rebates

No person shall allow or offer to allow either directly or indirectly, as an inducement to any person to take out or renew or continue an insurance in respect of any kind of risk relating to lives or property in India, any rebate of the whole or part of the commission payable or any rebate of the premium shown on the policy, nor shall any person taking out or renewing a policy accept any rebate, except such rebate as may be allowed in accordance with the published prospectus or tables of the insurer.

ANY PERSON MAKING DEFAULT IN COMPLYING WITH THE PROVISIONS OF THIS SECTION SHALL BE PUNISHABLE WITH FINE WHICH MAY EXTEND TO TEN LAKHS RUPEES.

Disclaimer: In the event of any question relating to interpretation of the insurance coverage, the policy document will prevail.