

Prospectus

This document is only a summary of the features of the Policy. Actual benefits available are as mentioned in the Policy, and are subject to its terms, conditions and exclusions.

Clinical Trial (Professional Liability) Insurance

Clinical trials always carry some risk including injuries resulting from the research procedure, administration of medication or medical procedures, or an investigator's failure to follow the protocol or the procedures correctly. Clinical Trial (Professional Liability) Insurance provides protection to insured against clinical Research Liability.



Scope of Cover:

Clinical Trial (Professional Liability) Insurance covers

1. Liability arising out of
 - Personal damages
 - Liability arising out of Material damages
 - Liability arising out of Damages arising from breaches of data protection
2. Cost of expert evaluations and reports
3. Other insurance benefits like
 - default interest,
 - mitigation,
 - expert, legal, court, arbitration, and commission costs etc

Dear Customer

We request you to kindly complete the Proposal form for this product and return it to us either direct or through your insurance adviser.

At SBIGIC we assure you a fair service when you step in as our customer in any of our offices.

If on any occasion our service falls below the standard you expect, you should contact your insurance adviser or alternatively the Branch Sales Head of the local branch.

If you feel that you require further assistance, then you can write to our office at



SBI General Insurance Co Ltd

'Natraj', 301, Junction of Western Express Highway & Andheri - Kurla Road, Andheri (East), Mumbai - 400 069.

Insurance is the subject matter of solicitation

Main Exclusions

- a) Personal damages and a deterioration of the existing state of health which would have occurred or persisted even without participation in the clinical trial;
- b) Personal damages that occurred because the trial subject deliberately, or apparently deliberately, contravened the express instructions of the people in charge of carrying out the clinical trial;
- c) Compensation for 'punitive damages';
- d) Damages arising from substances/formulations or preparations listed by the insurer (the insurance company). These substances/formulations or preparations must be listed by name in the "Insurance certificate for the attention of the ethics committees". Should contraceptive drugs be used as the trial drug or as a compulsory co- medication in the context of a clinical trial, any damages attributable to these contraceptives shall be covered.
- e) Personal damages to a patient in the control group, insofar as they are attributable to the application of a Drug product that has already been licensed for this indication. However, this does not exclude claims for personal damages attributable to a breach of the obligation to exercise due care by the policyholder or a third party commissioned by it to carry out the clinical trial.
- f) Personal damages to a patient that do not exceed a certain degree of adverse reactions that are to be expected from the trial drug according to the current state of medical knowledge, insofar and to the extent that comparably serious damages could have occurred if the patient had undergone a standard therapy to treat his illness.
- g) Personal damages to a patient that do not exceed a certain degree of adverse reactions that are to be expected from the trial drug according to the current state of medical knowledge, in the case of illnesses that ordinarily have a fatal outcome and insofar as no standard therapy exists to treat that illness

(Refer the policy wording for complete list of exclusion)

Who can take this insurance: -

This policy can be taken by Sponsor, Clinical Research Organisation (CRO), Institution or investigator(s) either jointly or severally.

Sum Insured: -

There will be an Aggregate Limit (the maximum limit of insurance in aggregate for all claims under the policy (AOY)) and also separate individual limit for single claim (AOA). Loss over and above said limit will be borne by insured.

In the event of a claim

Kindly approach SBIGIC through

- Toll Free Number
- Email notification
- SMS
- By letter /Fax
- Submitting manual claim form at any of SBIGIC's branch
- Via the Company website

Minimum info required

- Policy number
- Insured Name
- Date of loss
- Type of event

Claim Documentation

- Policy number
- Loss details such as
 - Type of Loss
 - Date of loss
 - Loss Location
- Contact details for communication
- Complete claim form duly filled in and signed, with supporting documents.

Basis of indemnity: -

There will be an Aggregate Limit (the maximum limit of insurance in aggregate for all claims under the policy (AOY)) and also separate individual limit for single claim (AOA).

The payment under the policy shall not exceed such Aggregate Limit and respective individual limit. The Aggregate Limit of Insurance and individual limit shall be reduced by the amount of any payment made under policy and respective coverage.

Premium/Payment of Premium:-

The rate of premium shall depend upon reinsurance quote. Payment of Premium should be accepted in full and in advance. Premium cannot be accepted in instalment.

Minimum Premium

As decided by reinsurer.

Period of insurance:

Policy can be issued either on trial period basis or annual basis as per reinsurance acceptance.

Deductibles

Deductibles will be determined as per reinsurance quote.

Cancellation:

It will be as mandated by reinsurance terms. For detail please refer policy terms and condition.

"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 or 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 or continuing a policy, accept any rebate except such rebate as may be allowed in accordance with the prospectuses or tables of the Insurer

Any person making default in complying with the provisions of this section shall be liable for a penalty, which may extend to Ten Lakh rupees."