SURAKSHA AUR BHAROSA DONO

CLINICAL TRIAL (PROFESSIONAL LIABILITY) INSURANCE
POLICY WORDING

1. Preamble and Operative clause

Whereas the Insured named in the Schedule hereto by a proposal and declaration has applied to the SBI General Insurance Company Limited for the insurance hereinafter contained and has paid the premium as consideration for this insurance.

The Company hereby agrees, subject to the terms, conditions and exclusions herein contained or endorsed or otherwise expressed hereon, to indemnify the Insured to the extent and in the manner specified herein.

2. Definitions

2.1 Personal damages

Personal damages are all damages as a result of death, injury or other harm to the health of the trial subjects.

These also include the economic consequences of insured personal damages, namely costs, loss of earnings taking into account the economic livelihood, damages sustained by the household, loss of maintenance payments (breadwinner damages), together with nominal damages (reparations).

2.2 Material damages

Material damages are all damages as a result of destruction, damage to or loss of material goods together with any resulting damage to the property of the injured party.

2.3 Damages arising from breaches of data protection

Breaches of data protection are material and nominal damages that arise from violations to personal integrity.

2.4 Drug products

Drug products are the medicinal products as described in the Drugs And Cosmetics Act, 1940 and which are to be tested in the clinical trial.

2.5 Trial series

A trial series is a group of several clinical trials on one active ingredient or one illness.

2.6 Clinical trial

"Clinical trial" means a systematic study of new drug(s) in human subject(s) to generate data for discovering and/or verifying the clinical, pharmacological (including pharmacodynamic and pharmacokinetic) and /or adverse effects with the objective of determining safety and / or efficacy of the new drug. (Section 122DAA of Drugs and Cosmetics Rules, 1945

2.7 Trial subject

Those persons (patients or healthy volunteers) who voluntarily take part in a clinical trial, whether they belong to the groups to which the Drug product is administered for testing or to a controlgroup

2.8 Sponsor (policyholder)

Any person or organization assuming responsibility for initiating, managing or financing a clinical trial.

3. Scope of the insurance policy

3.1 Object of the insurance policy

The insurance company offers insurance coverage in the event that, during an insured clinical trial carried out by the policyholder or on its behalf, any trial subjects involved are killed, physically injured, or suffer harm to their health (personal damages) or that any trial subjects suffer material damage in relation to the clinical trial.

3.2 Scope of the insurance policy

3.2.1 Personal damages

Insurance coverage is intended for personal damages suffered by a trial subject in relation to a clinical trial. The insurance coverage also extends to claims for personal damages caused by procedures carried out on trial subject in relation to the clinical trial on the Drug product.

The insurance company shall provide compensation for the damage actually occurred. The trial subject or, in the event of death, the persons supported by him/her, shall receive such compensation that he/she would receive on the basis of the legal requirements if a party were found liable towards him/her.

Should any illnesses that have arisen independently of the clinical trial or any other causes have played a role in the personal damages, the compensation shall only be paid in proportion to the part of the clinical trial relevant to the personal damages.

3.2.2 Material damages

The company shall also provide compensation for material damages suffered by the trial subject in relation to the clinical trial.

3.2.3 Damages arising from breaches of data protection

Insurance coverage exists for damages suffered from breaches of data protection in relation to the insured clinical trial. Such damages shall be considered as personal damages.

3.2.4 Cost of expert evaluations and reports

In insured cases, the insurance company shall bear the costs of any evaluation or report by an expert it has commissioned.

3.2.5 Other insurance benefits

Benefits provided by the insurance company, inclusive of related damage and default interest, mitigation, expert, legal, court, arbitration, and commission costs, compensation for the parties and all other insured costs, are limited to the insured amount Or sublimit stated in the policy, less the agreed excess.

3.3 Territorial coverage and prescription

The insurance includes, within the insured study, those clinical investigations that are carried out in India within the duration of the contract.

The coverage includes damages that occur during the insured period (i.e. in the duration of the contract and the post-trial insurance coverage).

In cases of doubt the personal damages are considered to have occurred at the time when the trial subject first consulted a physician for symptoms that on this occasion or subsequently were proved to be symptoms of the personal damages concerned.

Following expiry of the contract personal damages will also be covered under the conditions of the contract if they occur within 60 months following the expiry of the contract (posttrial insurance coverage).

4. Restrictions to the scope of the insurance policy

The insurance coverage does not extend to claims of the following nature:

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 re- actions 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 out- come and insofar as no standard therapy exists to treat that illness.

5. Premium

5.1 Basis for calculating the premium

The premium is calculated on the basis of the number of trial subjects taking part in the insured study or clinical trial for the duration of the contract.

5.2 Payment of premium and due balance

The provisional premium mentioned in the policy falls due on the first of policy period.
The definitive premium is calculated at the end of the contract or after the contract has been cancelled. For this the policyholder must supply the necessary information; the insurance company may consult all relevant documents to check this information. Supplementary premiums and reimbursements fall due for payment on delivery of the balance statement to the policyholder.

6. Obligations

6.1 Obligations of the policyholder

a) Should the policyholder carry out the clinical trial itself, it is obliged:
(i) To comply with the Indian legislation related to drugs
(ii) To inform the trial subjects about the existence of the obligations incumbent upon them as listed in paragraph 6.2 below.
b) Should the policyholder commission a third party to carry out the clinical trial, it must ensure that the third party adheres to the obligations mentioned in paragraph 6.1 letter a of these requirements.
c) Should any event occur whose probable consequences may affect this insurance, the policyholder must report it to the insurance company without delay. The insurance company must be notified of a death occurrence early enough so that it can, if necessary, arrange for a post-mortem at its own expense before the burial (subject to the rights of the deceased's family).
d) The policyholder is obliged, to the extent that it is able, to help the insurance company to ascertain the facts and reduce the damages.
e) On the request of the insurance company, the investigator must be instructed to draft a report on the personal damages and, after completion of the medical treatment, a final report, with the consent of the trial subject; in addition, it must be ensured that all other reports by the investigator requested by the insurance company are provided. In insured cases the insurance company bears the costs of the report, otherwise these are borne by the policyholder.
f) On condition that the personal damage has been reported and the trial subject has given consent, the investigator or any other physicians who are treating or examining the trial subject for other reasons, and the social insurance providers or any other insurer, if providing insurance that also covers personal damages, are to be authorized to provide the insurance company with information on request.
g) The policyholder is obliged to ensure that well-ordered records are kept about the trial subject. The records must in particular be kept in such a way that, should any damage to health occur, the events of the trial can be reconstructed for individual cases.

6.2 Obligations of the trial subject

a) For the duration of the clinical trial, the trial subject must inform the investigator at the next visit about any other illnesses or complaints that have arisen in the meantime and about any medication taken for such illnesses or complaints.
b) Personal damages that may have occurred as a consequence of the clinical trial must be reported to the investigator without delay.
c) The trial subject must take or submit to all the appropriate measures that help to identify the cause and the extent of the damage that has occurred, and that help to reduce such damage.

6.3 Breach of obligations

Should the policyholder, the third party commissioned by the policyholder to carry out the clinical trial, or the trial subject, breach the obligations incumbent upon them under the terms of this contract (cf. paragraphs 6.1 and 6.2) the insurance coverage shall cease, subject to the contents of paragraph 2 below, unless they can prove that the violation under the circumstances should be considered as accidental or that the damage would have occurred even had the obligations been fulfilled.
The breach of the obligations imposed by the insurance company on the policyholder or on the third party commissioned by it to carry out the clinical trial (paragraph 6.1), only entails the right of recourse by the insurance company against the policyholder, however not the cancellation of the insurance coverage of the trial subject. In such cases, under the insurance contract, the trial subject has a right to claim directly from the insurance company. The insurance company cannot make objections that arise from the insurance contract or from the Indian Law on insurance

contracts against the trial subject. The policyholder must reimburse the insurance company for the compensation paid.

7. Miscellaneous

7.1 Contract duration

The present contract is concluded for the duration mentioned in the contract details and ends on completion of the clinical trial.

Should the clinical trial not be completed by the planned expiry of the contract, the policyholder must notify the insurance company without delay so that it can extend the contract accordingly.

7.2 Reports to the company

All reports to the insurance company must be made in writing and sent to the appropriate office or the Indian head office of the insurance company.

7.3 Claim entitlement

The policyholder is entitled to exercise the rights under the insurance contract. However, the insurance company has the right to pay the trial subject the compensation directly and without deducting any excess; in such a case the policyholder must refund the excess to the insurance company, waiving any objections (subject to paragraph 6.3).

All rights and obligations applicable to the policyholder and the trial subject are applicable to their legal successors.

The insurance claims may not be transferred or pledged without the express consent of the insurance company

7.4 Any dispute concerning the interpretation of the terms, conditions, limitations and/or exclusions contained herein is understood and agreed to by both the Insured and the Insurance Company to be subject to Indian Law. Each party agrees to submit to the exclusive jurisdiction of the Courts of India and to comply with all requirements necessary to give such Court the jurisdiction. All matters arising hereunder shall be determined in accordance with the law and practice of such Court.

7.5 The Insurance Company may at any time cancel the Policy by sending the Insured 15 days notice by registered letter, at the Insured's last known address and in such event the Insurance Company shall refund to the Insured a pro-rata' premium for unexpired period of Insurance.

The Insured may also at any time cancel the Policy by giving a written notice to the Insurance Company and in such event the Insurance Company shall allow refund of premium at the Insurance Company's short period rates as per the Table given here below, provided no claim has occurred up to the date of cancellation.

Policy run period	% of Annual Premium Refundable
Up to one month	75% of annual rate
Up to three months	50%of annual rate
Up to six months	25% of annual rate
Exceeding six months	Nil

The Insurance Company shall not be bound to accept any renewal premium nor to give notice that such is due.

7.6 In no case whatsoever shall the Insurance Company be liable for any loss or damage after the expiry of 12 months from the happening of the loss or damage unless the claim is the subject of pending action or arbitration; it being expressly agreed and declared that if the Insurance Company shall disclaim liability for any claim hereunder and such claim shall not within 12 calendar months from the date of the disclaimer have been made the subject matter of a suit in a Court of law then the claim shall for all purposes be deemed to have been abandoned and shall not thereafter be recoverable hereunder.

7.7 "The parties to the contract may mutually agree and enter into a separate Arbitration Agreement to settle any and all disputes in relation to this policy.

Arbitration shall be conducted under and in accordance with the provisions of the Arbitration and Conciliation Act, 1996."

Grievance Redressal Mechanism

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:

Stage 1: Bima Bharosa

You can register your grievances with the regulator using the following link: https://bimabharosa.irdai.gov.in/Home/Home

Stage 2: Head – Customer Care

Alternatively, if you wish to register your grievances directly with us, you may write to the Head – Customer Care. We aim to respond to all Grievances within 7 days. In our initial acknowledgement of receipt letter, we will provide the name and title of the person that is handling your Grievance. This individual will have the authority necessary to investigate and resolve the Grievance.

Email: head.customercare@sbigeneral.in

Toll-Free Number: 1800 102 1111 (Available 24/7)

Stage 3: Grievance Redressal Officer (GRO)

In case, you are still not satisfied with the decision/resolution communicated by the above officer or have not received any response within 5 Business days, you may escalate the matter to the Grievance Redressal Officer (GRO) which will undergo a detailed case investigation, and we aim to resolve the issue within 7 days from the date of receipt of your Grievance at GRO Desk

Email: gro@sbigeneral.in

Designation: Grievance Redressal Officer

Phone: 022-45138021

Note: - The Company shall endeavour to maintain the regulatory TAT of 14 days in resolving your grievances.

Stage 4: Escalation to Insurance Ombudsman

If you feel that the response to your Grievance was unsatisfactory, or if you believe your concerns have not been adequately addressed by the company, you may escalate the matter to the Insurance Ombudsman.

Submit your Grievance online:
https://www.cioins.co.in/Ombudsman