

CLINICAL TRIALS LIABILITY POLICY – MEDEX PROSPECTUS



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Clinical Trials Liability Policy - Medex

Prospectus

Magma's Clinical Trial Liability Policy - Medex provides the Insured protection against legal liabilities arising out of clinical trial provided by them.

The Policy not only protects the Insured against suits and damages awarded by courts but also covers the defence costs incurred by them while contesting such claims.

What is covered?

The Insurers will indemnify the Insured for all damages or compensation and claimants costs and expenses that they become legally obligated to pay by reason of law or under the terms and conditions of any Compensation Agreement in respect of any Claim made by any Research Subject for Bodily Injury or Property Damage caused by an Occurrence which happens after the Retroactive Date within the Territorial Limits shown in the Policy Schedule and arises out of the Clinical Trial(s) stated in the Policy Schedule

Provided that

- (a) any such Claim is first made in writing against the Insured and notified to the Insurers during the Period of Insurance or within the Extended Reporting Period stated in the Policy Schedule.
- (b) the Insurers liability shall not exceed the Limit of Indemnity specified in the Policy Schedule

The Insurers will also pay Legal Costs in addition to the Limits of Indemnity

What is not covered?

The Insurers will not indemnify the Insured under this Policy for the following

(1) CONTINUED USE OF MEDICINAL PRODUCT

any liability arising out of a Research Subject's continued use of the medicinal product or device used during the Clinical Trial after the Clinical Trial has been completed.

(2) EMPLOYEES

any liability for Bodily Injury to any Employee unless such Employee is a Research Subject in the Clinical Trial(s) specified in the Policy Schedule

(3) EXISTING MEDICAL CONDITIONS / FAILURE TO PERFORM

any liability

- (a) for Bodily Injury arising from the aggravation of existing health impairments or the deterioration of which would (on the balance of probabilities) have occurred or continued whether or not the Research Subject had participated in the Clinical Trial
- (b) arising from any failure of any drug product or therapy under Clinical Trial to provide any therapeutic benefit

(4) FINES AND PENALTIES

any liability arising out of

- (a) fines penalties or liquidated damages
- (b) punitive exemplary or aggravated damages and/or any additional damages resulting from the multiplication of compensatory damages
- (c) compensation ordered or awarded by any court of criminal jurisdiction.

(5) HIV / AIDS

any liability arising out of any condition directly or indirectly caused by contributed to or arising from Human Immune Deficiency Virus (HIV), Acquired Immune Deficiency Syndrome Related Complex (ARC), Acquired Immune Deficiency Syndrome (AIDS), viral Hepatitis or any other blood borne disease or infection or any mutation, derivation or variation thereof other than liability arising out of the drug, treatment or product administered to or used by any Research Subject in the course of a Clinical Trial

(6) INFORMED CONSENT

any Clinical Trial performed without the appropriate informed written consent of each Research Subject being obtained prior to the participation of each Research Subject in the Clinical Trial.

(7) KNOWN CIRCUMSTANCES

any Claim arising out of an Occurrence which the Insured were made aware of prior to the inception of this Policy.

(8) RADIOACTIVE CONTAMINATION

any liability in respect of any Bodily Injury or any legal liability of whatsoever nature directly or indirectly caused by or contributed to by or arising from:

- (a) ionising radiations or contamination by radioactivity from any nuclear fuel or from any nuclear waste from the combustion of nuclear fuel,
- (b) the radioactive, toxic, explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof

(9) REGULATORY APPROVAL

any liability arising out of a Clinical Trial that has not received the appropriate regulatory approval

(10) RETROACTIVE DATE

any liability arising out of an Occurrence which happened prior to the Retroactive Date.

(11) TSE/CJD

any liability arising out of any condition directly or indirectly caused by contributed to or

arising from Transmissible Spongiform Encephalopathy (TSE) Creutzfeldt-Jakob Disease (CJD) variant Creutzfeldt-Jakob Disease (vCJD) or new variant Creutzfeldt-Jakob Disease (nvCJD).

(12) USA AND CANADA

any Claim made or suit brought against the Insured before any Court arbitrator or tribunal in the United States of America or Canada or in respect of the enforcement upholding or registration against the Insured by any Court arbitrator or tribunal outside United States of America or Canada for any damages awarded by any Court arbitrator or tribunal in United States of America or Canada

(13) WAR AND TERRORISM

any liability arising out of or in any way connected to War and Terrorism

CLAIM NOTIFICATION/ PROCESS:

If during the Period of Insurance the Insured shall give written notice to the Insurers in accordance with Claims Co-operation of this Policy of any specific event which the Insurers accepts may give rise to a Claim any Claim subsequently made against the Insured arising out of that event shall be deemed to have been first made against the Insured during the Period of Insurance regardless of when such Claim is actually made

It shall be a condition precedent to any liability of the Insurers to make any payment under this Policy that on the happening of any Claim or any Occurrence which may give rise to a Claim under this Policy, the Insured shall:

- (a) notify the Insurers in writing as soon as reasonably practicable, with full particulars.
- (b) make no admission of liability or offer promise of payment without the Insurers prior written consent.
- (c) inform the Insurers immediately of any impending prosecution inquest or fatal inquiry or civil proceedings and send to the Insurers every relevant document unanswered.
- (d) retain unaltered and unrepaired anything in any way connected with any Bodily Injury or Property Damage for as long as the Insurers may reasonably require.

(e) produce to the Insurers at the expense of the Insured such books of account or other business books or documents or such other proofs as may reasonably be required by the Insurers for investigating or verifying the Claim.

Depending on individual circumstance, reliance may be placed on the following documents and information/appropriate:

- (a) Detailed version about the incident / alleged misfeasance
- (b) Details of loss caused/injury/death/property damage including all available information on victims as well as estimated quantum of liability.
- (c) Steps taken by the insured to mitigate the loss.
- (d) Statements from witnesses, sketch plans, photographs, visual records of evidence/circumstance, video, etc.
- (e) Any other evidence in support of claim
- (f) Press reports
- (g) FIR/Investigation report of Police
- (h) Survey/Investigation Report; Survey Report on the damaged property of some other surveyor, if any
- (i) All notices/summons of the court
- (j) Post Mortem Report/Medical Certificate

- (k) Consumer Action Group/Society/Group representation/Report
- (n) Details of other Insurance
- (o) Legal opinion/ Expert's opinion on admission of liability / appeal
- (p) Details of claims, if any, preferred by the affected party / insured for the same loss from any other source.
- (q) Evidence of legal liability of the insured.

If the legal opinion expresses the likelihood of liability being pinned on the insurer in terms of the policy all possibilities must be explored for out of court/compromised settlement. This will ensure expeditious settlement, avoidance of possibly large/huge liability and adverse publicity.

In the event of an Award being passed by the appropriate authority, a copy of the Award may be obtained immediately. A legal opinion may thereafter be obtained and the merits of the case examined as to whether it is worthwhile going in for appeal.

RENEWAL CLAUSE

The Insurer shall not be bound to accept any renewal premium nor give notice to the Insured that such renewal is due. No receipt for renewal premium is valid except on the official form issued by the Insurer. Under normal circumstances renewal will not be refused except on the grounds of misrepresentation, fraud, non-disclosure of material facts or non-cooperation of the Insured. On renewal, the benefits provided under the Policy and/or terms and conditions of the Policy including premium rate may subject to change.

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 or continuing 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 liable for a penalty which may extend to ten lakhs rupees.

NOTE

For detailed policy terms and conditions, coverage, clauses, exclusions, definitions, cancellation, and other conditions please refer to our Policy and endorsement wording.