

# Clinical Trial Liability

## Insurance (Commercial)

### Policy

### Proposal Form

**MAGMA GENERAL INSURANCE LTD.****PROPOSAL FORM - Clinical Trials Liability Policy (Commercial)****GUIDELINES FOR COMPLETION OF THE FORM**

1. Please answer all questions fully and correctly. Where any question does not apply, please mention clearly that the same is not applicable.
2. Insurance is a contract of Utmost Good Faith requiring the Insured not only to disclose all material facts but also not to suppress any material facts in response to the questions in the proposal form. If you think any fact is material, please disclose it.
3. The Policy shall become voidable at the option of the Insurer, in the event of any untrue or incorrect statement, misrepresentation, non-description or on non-disclosure in any material particular in the proposal form/personal statement, declaration and connected documents, or any material information having been withheld by the proposer or any one acting on his behalf.
4. Kindly contact the Company's Offices or Agents for any doubts or clarifications on the proposal form.

**NOTE**

The liability of the Company does not commence until this proposal has been accepted by the Company and premium paid.

**DETAILS: Put a ( ✓ ) mark wherever applicable****COMPANY NAME AND ADDRESS:****PRODUCT INFORMATION:**

<b>PRODUCT DESCRIPTION:</b>
<b>Composition :</b>
<b>Manufacturing Process:</b>
Summary of hazards identified or anticipated, their causes and associated risks, and proposed mitigating action:
<b>Any registration for this product in another country already:</b>
<b>Past/ Other Trial data for this product:</b>
<b>DESCRIPTION OF INTENDED USE:</b>

<b>DOSE/DOSAGE FORM/ROA:</b>
<b>STUDY POPULATION:</b>
<b>OBSERVATION PERIOD:</b>
<b>EFFICACY END POINT:</b>
<b>PROBANDS</b>
<b>How many probands will participate?</b>

**Inclusion and exclusion criteria of the probands.**

Inclusion Criteria:

Exclusion Criteria:

**Profile of probands: age, sex, race, health status, co-medication**

---

**BACKGROUND INFORMATION**

---

Brief summary of all applicable clinical investigations or research conducted by the sponsor

---

**SUMMARY OF PLANNED MAJOR PRE-CLINICAL AND CLINICAL ACTIVITIES**

---

Time-Schedule for the trial

**Outline of planned feasibility and clinical evaluation protocols**

PROTOCOL SYNOPSIS

**NEED FOR THE STUDY**

**STUDY TITLE**

**INVESTIGATIONAL DRUG:**

**DOSE/DOSAGE FORM/ROA:**

**STUDY POPULATION:**

**SAMPLE SIZE:**

**CLINICAL PHASE:**

**OBJECTIVE**

**EFFICACY ENDPOINTS :**

**PRIMARY:**

**SAFETY MEASUREMENTS**

<b>RATIONALE</b>
<b>DATA ANALYSIS</b>
Details of each test as well as the purpose. Examinations planned during the trial (eg. blood parameters, x-ray...)
<b>PROTOCOL DEVELOPMENT RESOURCES:</b>
<b>COVERAGE REQUIRED:</b>
<b>Policy Period:</b>
<b>Limit of Liability Aggregate AOY:</b>
<b>Any one Accident Limit AOA:</b>
<b>Limit Per volunteer/Subject:</b>

**Territorial Scope of cover/Jurisdiction:****Premium amount (including GST):****Additional details:**

1) Are all trials/studies in full accordance with:

- a) Department of health requirements with protocols approved by an independent ethics committee?
- b) Royal College of Physicians recommendations?
- c) Applicable Government Department or Medical Body or Pharmaceutical Industry Body Guidelines?
- d) ICH Guidelines on Good Clinical Practice

2) Are all trials/studies conducted in India? If not show summaries of trials in each country

3) If applicable, are all rights of recourse retained against product manufacturers?

4) Are all volunteers tested for HIV and Hepatitis prior to entering trial?

5) Details of incidents during the last 5 years resulting in death injury, disease or illness to patients or volunteers or any circumstances, which might give, rise to claim for compensation.

6) Summary of trial/studies performed in the last twelve months: Date commenced, Title/description, country, phase, Number of volunteers.

**Pre-clinical supporting data:**

## Quality assurance:

## Analysis of the Study

### **Any additional information relevant to the Policy**

**Note:** Please use additional sheets if space is not sufficient to complete details

## Premium Payment Details:

Kindly select :  Cheque  DD  NEFT   
Cash

Payee Name/ Account Holder Name :

Amount in Rs.

Bank Account No.

Bank Name \_\_\_\_\_

PAN Number

*Documents to be attached as per requirement for fulfillment of KYC Norm*

GST Registered

**GSTIN Number**

**GST State**

Digitized by srujanika@gmail.com



"I/We hereby give my/our consent to the Company to verify and obtain my/our identity/address proof as well as the identity /address proof of the insured through Central KYC Registry or UIDAI or through any other permitted modes for the purpose of undertaking applicable KYC."

## INTERMEDIARY DETAILS

**Intermediary code:**

**Intermediary name:**

I, \_\_\_\_\_ (Full Name) in my capacity as an Insurance Advisor/Specified Person of the Corporate Agent/Authorized employee of the Broker/Relationship Officer, do hereby declare that I have explained all the contents of this Proposal Form, including the nature of the questions contained in this Proposal Form to the proposer including statement (s), information and responses(s) submitted by him/her in this Proposal Form to questions contained herein or any details sought herein will form the basis of the Contract of Insurance between the Company and the Proposer, if this Proposal is accepted by the Company for issuance of the Policy. I have further explained that if any untrue statement(s)/information/response(s) is/are contained in this Proposal Form / including addendum(s), affidavits, statements, submissions, furnished/ to be furnished, or if there has been a non-disclosure of any material fact, the Policy issued to his/her favour pursuant to this Proposal may be treated by the Company as null and void and all premium paid under the Policy may be forfeited to the Company.

License No./ID (Advisor/Corporate Agent/Broker/Relationship Officer)

Date: DD MM YYYY

Signature of the Insurance Advisor: \_\_\_\_\_

## AML Guidelines

I/we hereby confirm that all premiums paid / payable in future are from bonafide sources and not paid out of proceeds of crime and that such premiums are not disproportionate to my/our income. I / we understand that the Company has the right to call for documents to establish sources of funds and to cancel the insurance policy in case I / we are found guilty by any competent court of law under any of the statutes, directly or indirectly governing the prevention of money laundering law in India.

Date: DD/MM/YYYY

Signature of the Proposer: \_\_\_\_\_

Are you or any of the proposal applicants PEPs\* or a close relative/associate of PEPs\*?

YES  NO

If yes, please share the details of "Politically Exposed Persons"(PEPs):

\* (PEPs) are individuals who have been entrusted with prominent public functions by a foreign country, including the heads of States or Governments, senior politicians, senior government or judicial or military officers, senior executives of state-owned corporations and important political party officials

**Additional Information:**

Nationality: Indian

Non-Indian

If, Non-Indian, please specify Country:-----

**Type of Organisation:**

- (i) Corporations
- (ii) Trust
- (iii) Government
- (iv) Partnership
- (v) Non-Government Organisations
- (vi) Co-operatives
- (vii) Society
- (viii) Private Limited Company
- (ix) Public Limited Company
- (x) others, please specify-----

**Source of Funds:**

Business: ----- Salaried: ----- Others (please specify) -----

## DECLARATION

I/We agree that the Policy shall become voidable at the option of the Company, in the event of any untrue or incorrect statement, misrepresentation, non-description or non-disclosure in any material particular in the proposal form/personal statement, declaration and connected documents, or any material information has been withheld by me/us or anyone acting on my/our behalf to obtain any benefit under this Policy.

I/We, the undersigned hereby declare and warrant that the above statements are true, accurate and complete. I/We desire to effect an insurance as described herein with the Company and I/We agree that this proposal and declarations hereto shall be the basis of contract between me/us and the Company and I/We agree to accept a Policy subject to the conditions prescribed by the Company.

I/We agree that the issuance of Policy/Cover Note shall be subject to realisation of premium cheque.

I/We hereby agree and confirm that if the amount collected is less than the premium quoted or revised as per changes in sum proposed for insurance or scope of cover desired by me/us, the proposal shall be considered for acceptance for a reduced sum appropriate to the premium collected and the Policy shall be finalised accordingly.

I hereby consent to and authorize Magma General Insurance Limited to make welcome calls, service calls or any other communication (electronic or otherwise) with respect to the proposed or existing policy of Company from time to time and subject to the provisions of applicable law.

I wish to get all policy related communications on my Whatsapp (other app) number.

I/We hereby declare and undertake that the amount paid by me/us as premium for aforementioned policy is out of my/our lawful and declared source of income.

## VERNACULAR DECLARATION

I hereby declare that I have fully explained the contents of the proposal form and all other documents incidental to availing the insurance from **Magma General Insurance Limited** to the proposer in the language understood by him/her. The same has been fully understood by him/her and the replies have been recorded as per the information provided by the proposer. Replies have been read out to, fully understood and confirmed by the proposer.

Place: Proposer's Signature \_\_\_\_\_

Company stamp

Date: Name: \_\_\_\_\_ Designation: \_\_\_\_\_  
(DD-MM-YYYY)

**Prohibition of Rebates Under Section 41 of Insurance Law (Amendment) Act, 2015**

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.