

Proposal to Purchase an Insurance Policy for a Clinical Trial

For any Inquiry – 9873234419

Name of the Item: An Insurance Policy for a Clinical Trial

Scope of Work, coverage, and limits:

Place of Study and sponsor: All India Institute of Medical Sciences, New Delhi

The study will be conducted at 10 academic centres in India

Type of Clinical Trial: Investigator-initiated non-regulatory PHASE 2/3 clinical trial of an already approved repurposed drug 'Enoxaparin'

Duration of policy: 36 months; premium to be paid annually

Funding: Indian Council of Medical Research

Number of participants: 482 patients with acute pancreatitis will be enrolled in the trial: 241 in the standard of care plus intervention drug arm and 241 in the standard of care plus placebo arm

Disease: Acute Pancreatitis

Name of the intervention drug: Low-molecular weight heparin

Coverage Required:

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|---|------------------------------------|
| Limit of Liability Aggregate AOY | INR 2 crores |
| Any one Accident Limit AOA | INR 2 crores |
| Limit Per volunteer/ Research Subject | INR 25 lacs |
| Number of clinical trials Covered | One |
| Professional Indemnity coverage for 10 investigators involved (AOA:AOY - 1:1) for the duration of the trial | Limit INR 50 lacs per investigator |
| Territorial Scope of Cover | India |
| Policy Territory | India |
| Policy Jurisdiction | India |

Qualifying Criteria (Submit documentary proof):

1. Participating company's office should be Delhi-based
2. Previous trial insurance policy issued: at least two trials in the last financial year
3. The insurer should be registered and approved by IRDAI
4. The technical and financial bids should be submitted separately
5. Liability claims should be settled within 3 months