PROPOSAL TO PURCHASE CLINICAL TRIAL INSURANCE POLICY

For Any Enquiry- 9818571841

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 6 academic centres in India

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

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

Funding: Indian Council of Medical Research

Number of participants: 202 patients with severe acute pancreatitis; Drug and placebo will be given in 1:1 ratio

Coverage required:

Limit of Liability Aggregate AOY	INR 5 cr.
Any one Accident Limit AOA	INR 5 cr.
Limit Per volunteer/ Research Subject	INR 25 lakhs
Number of clinical trials Covered	1
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 last financial year.
3. 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

Scope of Work, coverage, and limits:

1. Details of the Proposer	
	(a) Name of Proposer(s)
	DR. SOUMYA JAGANNATH MAHAPATRA
	(b) Address and telephone no. of Proposer(s):
	ROOM NO. 3104, THIRD FLOOR, DEPARTMENT OF GASTROENTEROLOGY AND HUMAN NUTRITION UNIT, ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NEW DELHI-110029 PHONE NO.: +91 9990420767
	(c) CIN/PAN number:
	BLFPM1863A
	(d) What is the usual business of the Proposer(s) and how long engaged therein (Business):
	CLINICAL RESEARCH AND PATIENT CARE IN GASTROENTEROLOGY, ENGAGED SINCE 2015

2. Description of the clinical trial/study		
	(a) Name of clinical trial/study	
	STEROID THERAPY IN PATIENTS WITH ACUTE SEVERE PANCREATITIS FOR RESOLUTION OF ORGAN FAILURE: A RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED, MULTI-CENTRE TRIAL	
	(b) Details of clinical trial/study	
	A MULTICENTRIC, DOUBLE-BLIND, PLACEBO-CONTROLLED, PHASE-2 CLINICAL TRIAL EVALUATING THE EFFICACY AND SAFETY OF INTRAVENOUS METHYLPREDNISOLONE IN PATIENTS WITH ACUTE SEVERE PANCREATITIS TO DETERMINE IMPROVEMENT IN ORGAN FAILURE RESOLUTION.	
	(c) Phase of the clinical trial/study	
	PHASE 2	
	(d) Duration of the clinical trial/study	
	THREE YEARS	

	(e) Number of locations where the clinical trial/study would be held
	THE STUDY WILL BE CONDUCTED AT SIX TERTIARY CARE ACADEMIC CENTRES: • **DEPARTMENT OF GASTROENTEROLOGY AND HUMAN NUTRITION, ALL INDIA INSTITUTE OF MEDICAL SCIENCES (AIIMS), NEW DELHI (COORDINATING CENTRE)** • **DEPARTMENT OF GASTROENTEROLOGY, POSTGRADUATE INSTITUTE OF MEDICAL EDUCATION AND RESEARCH (PGIMER), CHANDIGARH** • **DEPARTMENT OF GASTROENTEROLOGY, CHRISTIAN MEDICAL COLLEGE (CMC), VELLORE** • **DEPARTMENT OF GASTROENTEROLOGY, GOVIND BALLABH PANT HOSPITAL, NEW DELHI** • **DEPARTMENT OF GASTROENTEROLOGY, ALL INDIA INSTITUTE OF MEDICAL SCIENCES (AIIMS), BHUBANESWAR** • **TRIAL MONITORING CDSA-THSTI, FARIDABAD**
	(f) Any past/other trial data for the intended clinical trial/study
	PILOT DATA SUGGEST POTENTIAL BENEFITS OF CORTICOSTEROIDS IN MODULATING INFLAMMATORY RESPONSE IN ACUTE PANCREATITIS; HOWEVER, ROBUST RANDOMIZED CLINICAL TRIAL DATA ARE LACKING.

(g) Outline of planned feasibility and clinical evaluation protocols (Protocol Synopsis):

ELIGIBLE PATIENTS WILL BE RANDOMIZED TO RECEIVE EITHER INTRAVENOUS METHYLPREDNISOLONE OR PLACEBO FOR 7 DAYS. PRIMARY ENDPOINT: RESOLUTION OF ORGAN FAILURE WITHIN 14 DAYS. SECONDARY ENDPOINTS: MORTALITY, DURATION OF HOSPITAL STAY, AND COMPLICATIONS.
(h) Need for the clinical trial/study:
NO ESTABLISHED ANTI-INFLAMMATORY THERAPY EXISTS FOR SEVERE ACUTE PANCREATITIS. EARLY STEROID INTERVENTION MAY MITIGATE SYSTEMIC INFLAMMATION AND MULTI-ORGAN DYSFUNCTION.
(i) Safety Measurements:
DAILY MONITORING OF VITALS, ORGAN FUNCTION SCORES (MODIFIED MARSHALL), AND LABORATORY PARAMETERS. **ADVERSE EVENTS REPORTING AND DATA SAFETY MONITORING BOARD OVERSIGHT.**
(j) Details of each test as well as the purpose [Examination planned during the clinical trial (eg, Blood parameters, x-rays, etc)]:

HEMATOLOGY, BIOCHEMISTRY, INFLAMMATORY MARKERS, IMAGING (ULTRASOUND/CT-SCAN), ORGAN FUNCTION ASSESSMENT TEST FOR RENAL, HEPATIC, AND PULMONARY.
(k) Description of the Product:
• **Composition: METHYPREDNISOLONE FOR INJECTION.** DAY 1 TO 3: 60 MG/ML DAY 4 AND 5: 40 MG/ML DAY 6 AND 7: 30 MG/ML
• Manufacturing Process: **AS PER GOOD MANUFACTURING PRACTICE (GMP) CERTIFIED FACILITY.**
• Summary of hazards identified or anticipated, their causes and associated risk, and proposed mitigating actions: **RISK OF HYPERGLYCEMIA, INFECTION; MONITORED BY DAILY CLINICAL AND LABORATORY ASSESSMENT.**
• Any registration for this product in another country already: **APPROVED FOR HUMAN USE.**
• Description of intended use: **ANTI-INFLAMMATORY THERAPY FOR ORGAN FAILURE IN SEVERE ACUTE PANCREATITIS**
• Dose/Dosage Form: **64, 48, AND 36 MG/KG/DAY INTRAVENOUS FOR SEVEN DAYS.**
• Observation Period: **28 DAYS POST-RANDOMIZATION.**
• Efficacy Endpoint: **RESOLUTION OF ORGAN FAILURE WITHIN 28 DAYS.**

3. Detail of the study population	
	(a) Number:
	202 PARTICIPANT WILL BE ENROLLED FROM ALL CENTRES.
	(b) Age Profile:

	PATIENTS ENROLLED: AGE GROUPS 12 AND 75.
	(c) Health Status:
	PATIENTS DIAGNOSED WITH ACUTE SEVERE PANCREATITIS WITH ORGAN FAILURE AT ADMISSION.
	(d) Inclusion/Exclusion criteria for research Subject (Major ones): AS STATED IN THE FORM-PER REVISED ATLANTA CLASSIFICATION AND PROTOCOL.
	INCLUSION CRITERIA 1. **DIAGNOSIS OF ACUTE PANCREATITIS AS PER REVISED ATLANTA CLASSIFICATION** 2. **PATIENTS PRESENTING WITHIN SEVEN DAYS OF THE ONSET OF PAIN** 3. **PRESENCE OF ANY ORGAN FAILURE (MODIFIED MARSHAL GRADE ≥ 2) I.E., CARDIOVASCULAR, RESPIRATORY, OR RENAL, AND APACHE II SCORE ≥ 8 OR SYSTEMIC INFLAMMATORY RESPONSE SYNDROME > 24 HOURS (SIRS SHOULD BE ASSESSED AT TWO TIME POINTS > 6 HOURS APART) OR BISAP SCORE > 3.** **EXCLUSION CRITERIA** 1. **PATIENTS WITH CHRONIC PANCREATITIS** 2. **PREGNANCY AND BREASTFEEDING** 3. **AGE < 12 YEARS OR > 75 YEARS** 4. **MAJOR COMORBIDITY SUCH AS DECOMPENSATED CIRRHOSIS, ADVANCED HEART FAILURE (STAGE D), SIGNIFICANT LUNG PARENCHYMAL OR AIRWAY DISEASE WITH NYHA GRADE ≥ 3, ADVANCED CHRONIC KIDNEY DISEASE (STAGE ≥ 4), UNTREATED HIV INFECTION, UNTREATED CANCER.** 5. **PATIENT ALREADY ON IMMUNE-SUPPRESSIVE THERAPY** 6. **MAJOR PSYCHIATRY DISORDERS SUCH AS PSYCHOSIS, SCHIZOPHRENIA, MAJOR DEPRESSION, BIPOLAR DISORDER, ETC.** 7. **UNCONTROLLED DIABETES (HBA1C > 8), UNCONTROLLED HYPERTENSION (SYSTOLIC BLOOD PRESSURE ≥ 140 MM HG AND DIASTOLIC BLOOD PRESSURE ≥ 90 MM HG AS PER EIGHTH JOINT NATIONAL COMMITTEE CRITERIA)** 8. **BRAIN DEAD PATIENT OR PATIENTS WITH TWO ORGAN FAILURE (EACH GRADE 4)** 9. **ACUTE CHOLECYSTITIS** 10. **ACTIVE TUBERCULOSIS** 11. **KNOWN ADRENAL INSUFFICIENCY** 12. **ACUTE GASTROINTESTINAL BLEED WITHIN LAST 7 DAYS**

	13. PRESENCE OF DISSEMINATED INTRAVASCULAR COAGULATION (DIC) **14. ENCEPHALOPATHY AS DEFINED BY GLASGOW COMA SCALE ≤ 9**

4. Extensions requested: **UPTO FULL LIMIT OF INDEMNITY**
5. The date from which Insurance is required**: JANUARY 2026**

6. Details of person(s) to be insured:

Name	Professional Qualification	Participation
DR SOUMYA JAGANNATH MAHAPATRA	MD, DM GASTROENTEROLOGY	PRINCIPAL INVESTIGATOR
DR PRAMOD GARG	MD, DM GASTROENTEROLOGY	CO-PI (AIIMS, DELHI)
DR SIDDHARTH SRIVASTAVA	MD, DM, GASTROENTEROLOGY	CO-PI (G.B. PANT HOSPITAL)
DR JAYANTA SAMANTA	MD, DM GASTROENTEROLOGY	CO-PI (PGIMER, CHANDIGARH)
DR SUDIPTA DHAR CHOWDHURY	MD, DM GASTROENTEROLOGY	CO-PI (CMC, VELLORE)
DR HEMANTA KUMAR NAYAK	MD, DM GASTROENTEROLOGY	CO-PI (AIIMS, BHUBANESWAR)
DR NITYA WADHWA	MD (PEDIATRICS)	CO-PI (THSTI, FARIDABAD)

7. Are the trials conducted in accordance with:

The requirements under the applicable statutes, rules, and regulations (including the Drugs and Cosmetics Act 1940 and Drugs and Cosmetics Rules 1945)	YES **[✓]** NO []
Protocols approved by an independent ethics committee?	YES **[✓]** NO []
Applicable Government Department or Medical Body or Pharmaceutical Industry Body guidelines?	YES **[✓]** NO []
CDSCO guidelines on Good Clinical Practice	YES **[✓]** NO []

I.C.H. Guidelines (when applicable)	YES **[√]** NO []

8. Coverage Required:

Limit of Liability Aggregate AOY	INR 5 cr.
Any one Accident Limit AOA	INR 5 cr.
Limit Per volunteer/ Research Subject	INR 25 lakhs
Number of clinical trials Covered	1
Territorial Scope of Cover	INDIA
Policy Territory	INDIA
Policy Jurisdiction	INDIA
Voluntary Deductible (for each and every **Claim** or series of **Claims** arising out of one **Occurrence** (**Legal Costs** inclusive))	NIL