PROPOSAL TO PURCHASE CLINICAL TRIAL INSURANCE POLICY

For Any Enquiry: 8586831628

Name of Item: Clinical Trial Insurance Policy for ACT Trial

Place of Study and Sponsor: AIIMS, New Delhi

Study Title: Effect of Timing of Biliary Drainage (Urgent versus Early) in Severe Acute Cholangitis on Recovery: A Multi-Centre, Open-Label Randomized Controlled Trial (ACT Trial).

Coordinating Centre: Department of Gastroenterology and Human Nutrition Unit, AIIMS, New Delhi.
Study Centres: Three tertiary-care academic centres: AIIMS New Delhi, PGIMER Chandigarh, and AIIMS Bhubaneswar.
Type of Trial: Investigator-initiated, multicentre, open-label, randomized controlled Phase II clinical trial.
Intervention: Urgent biliary drainage within 12 hours versus early biliary drainage between 12 and 48 hours, randomized 1:1.
Duration: 36 months (3 years); premium to be paid annually, as applicable.
Funding Agency: Indian Council of Medical Research (ICMR).
Participants: 136 patients with severe acute cholangitis across all participating centres.
Coverage Required:

Limit of Liability Aggregate AOY	4,00,00,000
Any one Accident Limit AOA	4,00,00,000
Limit Per volunteer/ Research Subject	15,00,000
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

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

PROPOSAL FORM FOR CLINICAL TRIAL INSURANCE POLICY

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	
	EFFECT OF TIMING OF BILIARY DRAINAGE (URGENT VERSUS EARLY) IN SEVERE ACUTE CHOLANGITIS ON RECOVERY: A MULTI-CENTRE, OPEN-LABEL RANDOMIZED CONTROLLED TRIAL (ACT TRIAL)	
	(b) Details of clinical trial/study	
	A MULTICENTRIC, OPEN-LABEL, RANDOMIZED CONTROLLED TRIAL EVALUATING CLINICAL RECOVERY IN PATIENTS UNDERGOING URGENT BILIARY DECOMPRESSION (WITHIN 12 HOURS OF PRESENTATION) COMPARED WITH EARLY BILIARY DECOMPRESSION (12-48 HOURS OF PRESENTATION) IN PATIENTS WITH SEVERE ACUTE CHOLANGITIS (SAC) AND ONGOING ORGAN FAILURE.	
	(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 THREE 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, ALL INDIA INSTITUTE OF MEDICAL SCIENCES (AIIMS), BHUBANESWAR**
	(f) Any past/other trial data for the intended clinical trial/study
	PILOT DATA SUGGEST THAT EARLY DRAINAGE, PREFERABLY WITHIN THE FIRST 24 HOURS OF PRESENTATION, HAS BETTER OUTCOMES COMPARED WITH DRAINAGE BEYOND 48 HOURS, WITHOUT ANY UNTOWARD ADVERSE EVENTS; 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 EITHER UNDERGO URGENT BILIARY DRAINAGE (WITHIN 12 HOURS) OR EARLY BILIARY DRAINAGE (12-48 HOURS). PRIMARY ENDPOINTS: 30-DAY ALL-CAUSE MORTALITY AND A HIERARCHICAL COMPOSITE OUTCOME OF CHANGE IN CLINICAL STATUS DURING THE 30 DAYS OF TREATMENT. SECONDARY ENDPOINTS: CLINICAL AND TECHNICAL SUCCESS, NEW-ONSET ORGAN FAILURE, OR WORSENING OF EXISTING ORGAN FAILURE WITHIN 30 DAYS.
(h) Need for the clinical trial/study:
MANY PROSPECTIVE AND RETROSPECTIVE STUDIES HAVE SHOWN THE BENEFIT OF EARLY BILIARY DRAINAGE IN REDUCING THE MORTALITY RATES,11–13 BUT THESE RESULTS WERE NOT PROVEN IN A RANDOMIZED CONTROLLED TRIAL. FURTHERMORE, THERE IS NO CLARITY REGARDING HOW EARLY THE BILIARY DRAINAGE SHOULD BE PERFORMED IN SAC I.E. WITHIN 12 HOURS OR WITHIN 48 HOURS. HENCE, WE AIM TO CONDUCT AN RCT TO COMPARE THE EFFECT OF URGENT BILIARY DRAINAGE WITHIN 12 HOURS VERSUS EARLY BILIARY DRAINAGE BETWEEN 12 TO 48 HOURS IN PATIENTS WITH SEVERE ACUTE CHOLANGITIS.
(i) Safety Measurements:
DAILY MONITORING OF VITALS WILL BE PERFORMED. ANY NEW SYMPTOM OR SIGN DURING AND AFTER THE STUDY INTERVENTION WILL BE RECORDED. ADVERSE EVENT REPORTING AND DATA SAFETY MONITORING BOARD OVERSIGHT WILL BE MAINTAINED.

(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), AND ORGAN FUNCTION ASSESSMENT FOR RENAL, HEPATIC, AND PULMONARY FUNCTION.
(k) Description of the Product:
NA
• Manufacturing Process:
• Summary of hazards identified or anticipated, their causes and associated risk, and proposed mitigating actions:
• Any registration for this product in another country already:
• Description of intended use:
• Dose/Dosage Form:
• Observation Period:
• Efficacy Endpoint:

3. Detail of the study population	
	(a) Number:
	136 PARTICIPANTS WILL BE ENROLLED FROM ALL CENTRES.
	(b) Age Profile:
	PATIENTS ENROLLED: AGE 18 TO 70 YEARS.

	(c) Health Status:
	PATIENTS DIAGNOSED WITH SEVERE ACUTE CHOLANGITIS.
	(d) Inclusion/Exclusion criteria for research Subject (Major ones)
	INCLUSION CRITERIA **Patients with severe acute cholangitis as defined by Tokyo guidelines 2018 as follows:** **It will be defined as acute cholangitis that is associated with the onset of dysfunction at least in any one of the following organs/systems:** **1. Cardiovascular dysfunction: hypotension requiring dopamine ≥5 µg/kg/min or any dose of norepinephrine/ epinephrine** **2. Neurological dysfunction: any disturbance in consciousness** **3. Respiratory dysfunction: PaO2/FiO2 ratio <300** **4. Renal dysfunction: oliguria, serum creatinine > 2.0 mg/dl** **5. Hepatic dysfunction: PT-INR > 1.5** **6. Hematological dysfunction: Platelet count < 100,000/cumm** **EXCLUSION CRITERIA** **1. Patients with age <18 or >70 years.** **2. Patients with refractory shock requiring dopamine >15 mcg/kg/min or epinephrine > 0.3 mcg/kg/min or norepinephrine > 0.3 mcg/kg/min or requiring two inotropic drugs simultaneously** **3. Patients on mechanical ventilation due to severe respiratory failure or poor GCS (< 6)** **4. Moribund patients with expected survival less than a month such as advanced malignancy** **5. Severe co-morbidities such as decompensated cirrhosis or chronic renal failure or congestive heart failure** **6. Pregnancy** **7. Patients with malignant hilar obstruction, Bismuth Corlette type II-IV** **8. Patients refusing consent**

4. Extensions requested: **UPTO FULL LIMIT OF INDEMNITY**

- Notification of Event or Circumstance _____

- Manslaughter Defence Costs (Ethics Committee) _____
- Additional Insured (Sponsors) _____
- Extended Reporting Period _____

Please provide details and particulars applicable for the extensions requested above:

_____

5. The date from which Insurance is required**: 01 JUNE 2026**
6. Details of person(s) to be insured:

Name	Professional Qualification	Participation
DR PRAMOD GARG	MD, DM GASTROENTEROLOGY	CO-PI (AIIMS, DELHI)
DR SOUMYA JAGANNATH MAHAPATRA	MD, DM GASTROENTEROLOGY	PRINCIPAL INVESTIGATOR
PROF SHIVANAD GAMANAGATTI	MD RADIODIAGNOSIS	CO-PI (AIIMS, DELHI)
DR DEEPAK GUNJAN	MD, DM GASTROENTEROLOGY	CO-PI (AIIMS, DELHI)
DR JAYANTA SAMANTA	MD, DM GASTROENTEROLOGY	CO-PI (PGIMER, CHANDIGARH)
DR HEMANTA KUMAR NAYAK	MD, DM GASTROENTEROLOGY	CO-PI (AIIMS, BHUBANESWAR)

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. Details of incidents during the last 5 years resulting in death, injury, disease, or illness (physical or mental) to Research Subjects and any circumstances which might give rise to a claim of compensation against you.

PLEASE REFER THE PROTOCOL

9. Does any proposed Insured have knowledge or information of any act, error, or omission which might reasonably be expected to give rise to or result in a Claim under the policy?
10. Have all necessary licenses, permits been obtained, and have all contractual arrangements been confirmed in writing? If no, give details.

ALL NECESSARY ETHICS COMMITTEE, AND INSTITUTIONAL PERMISSIONS OBTAINED.

11. In case the insured wants a floater policy covering annual trials in one policy, they are required to provide the information in points 2,3,4,5,6, and 7 with respect to all trials. If trials overlap period, please include in both tables, allocating the appropriate number of Research Subjects to each timescale.

Summary of trials planned for the next 12 months: **NOT REQUIRED**

DATE COMMENCED/FINISHED	TRIAL/TITLE/DESCRIPTION	PHASE	NO OF RESEARCHER SUBJECTS	Duration

12. Coverage Required:

Limit of Liability Aggregate AOY	4,00,00,000
Any one Accident Limit AOA	4,00,00,000
Limit Per volunteer/ Research Subject	15,00,000
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

13. In order for us to efficiently process your proposal, please attach the following to your signed proposal:
    (a) Copy of the Protocol document, as approved by the applicable committee. (b) Copy of the regulatory approval received in relation to the Clinical Trial/Protocol, and any other material communication received from the applicable governmental or regulatory authority in this regard.

Note: Please note that all written statements and materials furnished to the company accepting this proposal, in conjunction with this proposal, are hereby incorporated by reference into this proposal and made a part hereof.

PROHIBITION OF REBATES (Section 41 of the Insurance Act 1938 provides)

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 punishable with fine, which may extend to ten lakh rupees.

DECLARATION

To the best of my knowledge and belief, the information provided in connection with this proposal, whether in my own hand or not, is true, and I have not withheld any material facts. I understand that non-disclosure or misrepresentation of a material fact will entitle Underwriters to void the insurance.

(N.B. A material fact is one likely to influence acceptance or assessment of this proposal by Underwriters: if you are in any doubt as to what constitutes a material fact, you should consult your Broker.)

I understand that the signing of this proposal does not bind me to complete or Underwriters to accept this insurance, but agree that, should a contract of insurance be concluded, this proposal and the statements made therein shall form the basis of the contract.

Proposer's Name: **Dr. SOUMYA JAGANNATH MAHAPATRA**

Position: **ASSISTANT PROFESSOR, DEPARTMENT OF GASTROENTEROLOGY, AIIMS NEW DELHI**