

## Claim Reporting Form - Clinical Trials Liability Insurance

**(The issue of this form is not to be taken as an Admission of Liability)**

All Non-fatal, serious adverse events, which occur in a patient enrolled in a study are to be reported within 24 hours of knowledge.

### 1. Insured details

Name:

Address:

Telephone number:

E-mail id:

Policy no.

Expiry date:  Retro date:

Are you or any of the proposed applicants/beneficial owner a PEP\* or Family member/Close relatives/Associates of PEP\*?

☐ Yes ☐ No

If yes, please give details (Nature of relationship and position held by PEP):

"Politically Exposed Persons" (PEPs) are individuals who have been entrusted with prominent public functions by a foreign country, including the heads of States / Government, senior politicians, senior government/judicial/military officers, senior executives of state-owned corporations and important political party officials;".

### 2. Details of the trial in respect of which the adverse event reported

Protocol Number:

Protocol Title:

Principal Investigator:  Date of Event:

### 3. Details of the 'study subject'

Number of subjects administered the trial drug:

Number of subjects affected:

Name of the patient:  Age & sex:

Complete address of the patient:

Name of Patient:

Medical Record number

4. Was the possibility of the event addressed in the protocol and consent? ☐ Yes ☐ No

5. Please check one category: The adverse event was:

- a. Highly related to the drug or device
- b. Likely related to the drug or device
- c. Unrelated to the drug or device
- d. Possibly related to the drug or device
- e. Relationship to drug or device unknown

6. Should the consent form be modified? ☐ Yes ☐ No

(If yes, a revised copy of the consent form should be submitted)

### ICICI Lombard General Insurance Company Limited

IRDA Reg. No. 115  
Mailing Address:  
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Mumbai - 400 064.

CIN : L67200MH2000PLC129408  
Registered Office Address:  
ICICI Lombard House, 414, Veer Savarkar Marg,  
Near Siddhivinayak Temple, Prabhadevi,  
Mumbai 400 025.

CLAIM REPORTING FORM - CLINICAL TRIALS LIABILITY INSURANCE  
Toll free no : 1800 2666  
Alternate no : 8655222666 (Chargeable)  
E-mail : customersupport@icicilombard.com  
Website : www.icicilombard.com

UIN: IRDAN115RP0018V01200607 (Retail)

7. Please check one category:

- a. Outcome:
- b. Resolved
- c. Unresolved
- d. Death

8. Are any protocol revisions required? ☐ Yes ☐ No  
(If yes, attach a description of the proposed changes)

9. Action - study drug / device was:

- a. Reduced
- b. Stopped temporarily
- c. Permanently discontinued
- d. No action necessary

10. Details of the incident/event:

- a. Incident Type:
- b. Date of Incident:
- c. Date Reported:
- d. Incident Region:
- e. Incident location:
- f. Witness:
- g. Injured Person or Potential Claimant:
- h. Incident Description\*:
- i. Alleged Cause:
- j. Remedial Action:
- k. Date Completed:
- l. Cost of Incident:
- m. Reporter's Name:
- n. Reporter's Phone:
- o. How was SAE discovered (e.g. new, routine exam, follow-up)?
- p. For all serious adverse events (SAEs):

(\*Comments should be factual and objective. Unless aspects are known to be true, they should be recorded as allegations or possibilities)

|               |            |                                                               |                                                                                                                                                                     |                                                                                                   |                                                                                                                                   |                                                                         |                                                                                                                                                             |
|---------------|------------|---------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------|
|               |            |                                                               |                                                                                                                                                                     |                                                                                                   |                                                                                                                                   |                                                                         |                                                                                                                                                             |
| Protocol:     |            |                                                               |                                                                                                                                                                     |                                                                                                   |                                                                                                                                   |                                                                         |                                                                                                                                                             |
| Investigator: |            | <input type="checkbox"/> Drug <input type="checkbox"/> Device | Drug/Device Name:                                                                                                                                                   |                                                                                                   | Lot number:                                                                                                                       |                                                                         |                                                                                                                                                             |
| Patient ID    |            | <input type="checkbox"/> Male <input type="checkbox"/> Female | Age:                                                                                                                                                                |                                                                                                   |                                                                                                                                   |                                                                         |                                                                                                                                                             |
| Event         | Onset Date | Stop Date                                                     | UNEXPECTED<br>Yes <input type="checkbox"/><br>No <input type="checkbox"/><br><br>LIFE<br>THREATENING<br>Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Severity:<br><br>[1 = mild<br>2 = moderate<br>3 = severe<br>4 = life<br>threatening<br>5 = fatal] | Relationship<br>to Study<br><br>Drug/Device:<br>[1 = definite<br>2 = probable<br>3 = possible<br>4 = unlikely<br>5 = not related] | Action<br>Taken:<br><br>[1 = none<br>2 =<br>medication<br>or<br>other*] | Clinical Outcome:<br><br>1 = resolved<br>2 = improved<br>3 = unchanged<br>4 = worsened<br>5 = hospitalization<br>6 = death<br>7 = insufficient<br>follow-up |

\*Any Action Taken that is listed as "medication" or "other" must be described below.

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| Rep No. | Age | Sex | Adverse Event | Relationship between Adverse Event & Trial Medication | Outcome or ongoing sequelae or other comments | Did this occur at SH.                                       | Does this Adverse Event need to be listed in the Patient Information Sheet (If no, comment below) | Patient Exc Criteria                                        | Patient Monitoring                                          | Patient Withdrawal Criteria                                 |
|---------|-----|-----|---------------|-------------------------------------------------------|-----------------------------------------------|-------------------------------------------------------------|---------------------------------------------------------------------------------------------------|-------------------------------------------------------------|-------------------------------------------------------------|-------------------------------------------------------------|
| 1       |     |     |               | Almost certainly<br>Probable<br>Possible<br>Unlikely  |                                               | Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                                       | Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Yes <input type="checkbox"/><br>No <input type="checkbox"/> |
| 2       |     |     |               | Almost certainly<br>Probable<br>Possible<br>Unlikely  |                                               | Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                                       | Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Yes <input type="checkbox"/><br>No <input type="checkbox"/> |
| 3       |     |     |               | Almost certainly<br>Probable<br>Possible<br>Unlikely  |                                               | Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                                       | Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Yes <input type="checkbox"/><br>No <input type="checkbox"/> |
| 4       |     |     |               | Almost certainly<br>Probable<br>Possible<br>Unlikely  |                                               | Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Yes <input type="checkbox"/><br>No <input type="checkbox"/>                                       | Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Yes <input type="checkbox"/><br>No <input type="checkbox"/> | Yes <input type="checkbox"/><br>No <input type="checkbox"/> |

-If yes, please fill in Comments Section

-SAEs are to be reported within seven (7) days or an explanation must be provided.

Details of Other Insurance covering same risk \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

#### Claim Clause/ Settlement of Claim:

- 1) Claim Intimation: Connect with us via: Toll-free no.: 1800 2666,

Email ID: customersupport@icicilombard.com, on our

website: <https://coclaims.icicilombard.com/claimstracker/CommercialClaims/ccplandingpage.aspx>

Register the claim and submit claim related documents along with claim form. You will receive a claim reference number as your reference point for future correspondence.

- 2) File an FIR: In case of third-party property damage/bodily injury, fire etc. if applicable as per policy terms and conditions.
- 3) Surveyor Appointment: Your Claims Manager (CSM) will contact you and appoint a licensed surveyor basis claim eligibility within 24 hours of reporting the claim
- 4) Documents: submit documents to the assigned CSM/Surveyor.

List of documents which are necessary and relevant to the claim are as below:

1. Claim bill / Claim Form duly filled up

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2. Photographs / Video of damaged property/item under claim
  3. Document/s in support of admissibility of the claim, for instance, all proceedings filed before the courts, communications exchanged with the insured, invoices, payment proofs, internal/external investigation report of the insured, Insureds counsel opinion on merits and demerits of the case, insured counsel engagement letter etc.
  4. FIR / Final Police investigation report wherever applicable
  5. For items which are to be repaired or reinstated, repair/ replacement quotation, invoice and payment proofs for each and every item as claimed.
  6. For items which are under claim & not to be repaired or reinstated, documents substantiating the quantum & value of the items under claim
  7. Offer for retention of salvage, if any
  8. KYC / NEFT Details as per AML guidelines
  9. Invoice copy / Goods Receipt Note / Monetary Claim on carrier / Damage Certificate
  10. Any other document which may be specified by the surveyor post completion of initial survey
- 5) Assessment Approval: Repair/Replacement details submitted in support of the claim will be assessed and approved by CSM/surveyor
- 6) Salvage: The amount that is assessed which the damaged asset will fetch in the open market (wherever applicable).
- 7) Turnaround Time (TAT): Assessment sheet /Survey report will be furnished within 15 days of receipt of claim form and documents. Claim will be decided within 7 days of receipt of the assessment sheet / survey report, as applicable.

**Attachments for this purpose: -**

- a. Brief description of the adverse event, actions taken and the outcome
  - b. Copies of sponsor reports
  - c. Informed consent forms signed by subjects
  - d. Trial Protocol document
  - e. Copy of GCP guidelines
- I/We hereby agree, affirm and declare that:
- f. The statements/information given/stated by me/us in this claim form are true, correct and complete.
  - g. The details of all persons having an interest in the property in respect of which the claim is being made are provided as per the proposal form or by way of an endorsement in the policy. Furthermore, save and except as provided or disclosed in this claim form, no claim made hereunder (or the same/similar claim) has been made or lodged with any other insurance company.
  - h. No material information which is relevant to the processing of the claim or which in any manner has a bearing on the claim has been withheld or not disclosed.
  - i. If I/we have given/made any false or fraudulent statement/information, or suppressed or concealed or in any manner failed to disclose material information, the policy shall be void and that I/We shall not be entitled to all/any rights to recover thereunder in respect of any or all claims, past, present or future.
  - j. The receipt of this claim form/other supporting/related documents does not constitute or be deemed to constitute an agreement by the Company of the claim and the Company reserves the right to process or reject or require further/additional information in respect of the claim.

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 / Beneficial Owner through Central KYC Registry or UIDAI or through any other modes for the purpose of undertaking KYC.

Signature of the insured: \_\_\_\_\_ Date: \_\_\_\_\_

(Name: \_\_\_\_\_)

Date - Month - Year

Designation: \_\_\_\_\_)

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