

# Clinical trial liability insurance (no fault compensation)

Clinical trial liability insurance safeguards both researchers and participants, covering harm caused by negligence as well as harm where no fault is found. It provides for legal defense expenses as well as compensation payments.

## KEY POINTS

- **Coverage:** Insurance protects against legal liabilities from participant injuries or death, covering legal costs and compensation claims.
- **Risk Management:** Insurance is essential for financial stability, focusing on research without the burden of litigation risks, customizable based on trial specifics.
- **Claims-made policy:** Insurance covers claims made during the policy period and extended reporting period (if required).
- **Country Specific Law:** Insurance policies and provisions are governed by the legal requirements of the country hosting the clinical trial.
- **Syndicated at Lloyd's:** Insurance is backed by a group of insurers at Lloyd's of London (Brussel), by offering strong financial security and access to a wide range of insurance expertise.

## INFORMATION NEEDED TO OBTAIN A QUOTE

- Request form to be filled in (example below)
- Protocol or Ethics Committee submission
- Patient/volunteer information
- Patient/volunteer consent form
- Any hold harmless agreement/contract indemnities with other parties (if applicable)

Quote back within 24 hours\*

\*provided all information submitted is full and comprehensive

## Please send the request form to:

Mrs Signe Soonberg | health-specialised insurance broker  
ssoonberg@northern1.eu | +37256054189

Broker background:

- 1996 - 2000 Regulatory affairs inspector State Agency of Medicines Estonia
- 2000 - 2010 Country Manager Estonia of Swiss medical company Mepha (currently Teva)
- 2014 - 2024 Health-focused insurance broker at Northern1

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# Proposal form - single trials

**EXAMPLE**

## Important Notice

This Proposal form is for a “claims made” policy. A “claims made” policy provides indemnity in respect of claims first made against the Insured and notified to insurers during the period of insurance.

“Claims made” policies also provide indemnity in respect of claims first made against the Insured after the period of insurance which arise from circumstances properly notified to insurers during the period of insurance.

Please complete each question fully using black or blue ink and enter “N/A” if not applicable. Any unanswered questions will delay a quotation. Should there be insufficient space on the Proposal form to provide a complete answer or if additional information or material is necessary, additional sheets should be used and attached to this Proposal form.

Please sign and date this Proposal form.

It is the duty of the proposed Insured to complete this Proposal form accurately and to disclose all material facts and circumstances. Please consult with your insurance broker, other intermediary or ourselves if you are unsure how to comply with this duty or the consequences of breach of this duty.



[www.northern1.eu](http://www.northern1.eu)



[info@northern1.eu](mailto:info@northern1.eu)



Veskiposti 2-1002 Tallinn Estonia

## SECTION 1: GENERAL INFORMATION

1. Name of company or body to be Insured:

2. Address:

3. Telephone number:

4. Employer Reference Number (ERN):

5. Companies House Number

6. Fax number:

7. Website:

8. Description of business:

9. Date established:



## SECTION 1: GENERAL INFORMATION CONTINUED

PLEASE COMPLETE THE FOLLOWING DECLARATION - Give full details if any reply is "No".

8. Are all trials are conducted in full accordance with:

- a) Department of Health requirements with protocols approved by an independant Ethics Committee? Yes  No
- b) Royal College of Physicians recommendations? Yes  No
- c) Applicable Government Department or Medical Body or Pharmaceutical Insudtry Body guidelines? Yes  No
- d) E.C. Guidelines on Good Clinical Practice? Yes  No
- e) I.C.H. Harmonised Tripartite Guidelines? Yes  No

9. If applicable, are all rights of recourse retained against Trial Sponsors and/or Product Manufacturers? Yes  No

10. Give details of serious adverse events during the last five (5) years resulting in death, injury, disease or illness (physical or mental) to research subject, and any circumstances which has given or might give rise to a claim against you in connection with the Trial/Trial Drug(s), procedures for which coverage is sought hereon. **(Please use additional space if needed)**

11. For each trial please attach a copy of:

- a) PROTOCOL (or summary thereof) or ETHICS COMMITTEE SUBMISSION
- b) PATIENT/VOLUNTEER INFORMATION (if not corporated into the Protocol)
- c) PATIENT/VOLUNTEER CONSENT FORM (if not incorporated into the Protocol)
- d) ANY HOLD HARMLESS AGREEMENT/CONTRACT INDEMNITIES WITH OTHER PARTIES (if applicable)

12. Please state Limit(s) of Indemnity for which a quotation is required or local currency equivalent:

- a) €1,000,000
- b) €2,000,000
- c) €3,000,000
- d) €4,000,000
- e) €5,000,000

f) If higher, please state, €

13. Please state whether you require quotations for extended discovery periods (after epiration of the policy period or duration of the trial):

- a) 12 months Yes  No
- b) 24 months Yes  No



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## SECTION 2: DECLARATION

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### Important Notice

A Director, Company Secretary or Legal Representative of the proposed Insured must complete this Proposal Form. All questions must be answered to enable a quotation to be given. This Proposal Form must be signed and dated.

### Declaration

I am authorised to complete this Proposal Form on behalf of the proposed Insured.

*Please tick the box for the statement below that applies to the proposed Insured.*

FOR PROPOSED POLICIES SUBJECT TO THE INSURANCE ACT 2015 (England and Wales Law and Jurisdiction)

I am aware of the duty of fair presentation under the Insurance Act 2015 and our responsibilities and those of our agents to accurately disclose all material circumstances in accordance with the requirements of the Act. We understand that if the duty of fair presentation is not complied with, we may not be able to rely upon some or all of the terms of any policy issued in reliance on this Proposal Form or other statements may by or on our behalf.

FOR THE PROPOSED POLICIES NOT SUBJECT TO THE INSURANCE ACT 2015

I confirm that I have completed this Proposal Form accurately and have disclosed all material facts and circumstances.

Name:

Position:

Signed:

Date:



## ADDITIONAL SPACE

PLEASE USE THIS SPACE TO RECORD THE ANSWERS TO ANY QUESTIONS FOR WHICH YOU REQUIRE ADDITIONAL SPACE, NOTING THE APPROPRIATE QUESTION NUMBER

