

Proposal form

Clinical research contractors' professional and public liability insurance (EUR)



Important notice

For the Proposer:

1. Before the insurance contract is entered into, the proposer must make a fair presentation of the risk to the insurer, in accordance with Section 3 of the Insurance Act 2015.

In summary, the proposer must:

- a) disclose to the insurer every material circumstance which the proposer knows or ought to know. Failing that, the proposer must give the insurer sufficient information to put a prudent insurer on notice that it needs to make further enquiries in order to reveal material circumstances. A matter is material if it would influence the judgement of a prudent insurer as to whether to accept the risk and, if so on what terms (including premium);
 - b) make the disclosure in clause a) above in a reasonably clear and accessible manner; and
 - c) ensure that every material representation as to a matter of fact is substantially correct, and that every material representation as to a matter of expectation or belief is made in good faith.
2. For the purposes of clause a) above, the proposer is expected to know the following:
 - a) If the proposer is an individual, what is known to the individual and anybody who is responsible for arranging his or her insurance.
 - b) If the proposer is not an individual, what is known to anybody who is part of the proposer's senior management; or anybody who is responsible for arranging the proposer's insurance.
 - c) Whether the proposer is an individual or otherwise, what should reasonably have been revealed by a reasonable search of information available to the proposer. The proposer cannot ignore or deliberately withhold information (this may amount to a breach of the duty of fair presentation even if the insurer had sufficient information to ask questions and did not do so). The information may be held within the proposer's organisation, or by any third party (including but not limited to subsidiaries, affiliates, the broker, or any other person who will be covered under the insurance). If the proposer is insuring subsidiaries, affiliates or other parties, the insurer expects that the proposer will have included them in its enquiries, and that the proposer will inform the insurer if it has not done so. The reasonable search may be conducted by making enquiries or by any other means.

If the proposer becomes aware that information provided prior to confirmation of insurance cover was incorrect or incomplete the proposer should tell us immediately.

If in doubt, please contact Miller's Life Sciences team

For the Insurer:

Insurers agree that the format of this proposal form presents information in a reasonably clear and accessible manner; and the questions asked in the proposal form to be their own and are sufficient for underwriting purposes unless specified otherwise.

Proposal form



Data protection

Processing of personal data

If you provide us with any information which constitutes “personal data” (including any “sensitive personal data”), both you and we will treat such information at all times in accordance with “Data Privacy Laws” (including the UK Data Protection Act 2018 and the General Data Protection Regulation 2016/679). Miller companies may hold and process such information: (i) in order to provide our services to you; (ii) to facilitate the effective management, development or operation of the Miller companies; and (iii) in any country – including countries outside the European Economic Area, which many not have comparable data protection laws.

We may disclose your personal data in certain circumstances including, for example, (a) in the normal course of negotiating, maintaining or renewing your insurance policies. Our full privacy notice contains the complete list of circumstances.

We may also: (b) share information concerning your insurance arrangement with insurers where this is necessary to enable insurers to decide whether to participate in any arrangement made by Miller whereby participating insurers agree to automatically insure (wholly or partly) a portfolio of risks by delegating their authority to bind individual risks within such portfolio to the lead insurer or Miller.

Please review our full privacy notice at www.miller-insurance.com.

Identity verification

In order to ensure compliance with rules imposed on us by relevant UK regulators, we may run fraud prevention checks against the name of your firm, or all or any of the individual partners or members in your firm. We may use this information in order to comply with our regulatory, legal or good governance obligations. We will make checks such as verifying your identity in order to prevent and detect crime, fraud and money laundering. We may disclose your personal data to other companies in the Miller group of companies for the purposes described above. You agree to bring the above notice to the attention of each of your partners or members before completing and submitting this proposal form. Each individual has the right to apply for a copy of their information (for which we may charge a fee) and to have any agreed inaccuracies corrected.

- By ticking here, you agree to the processing of your personal data, including, where relevant, sensitive personal data, in the manner stated above in the paragraph entitled ‘Processing of personal data’.
- Please tick this box if you would like to subscribe to receive the latest news and insights from Miller Insurance Services LLP and its associated companies. Your information will not be passed to any third parties and you may unsubscribe at any time.

Proposal form



Proposer

If required, name of company to be insured

Address

Email

Telephone

Date of establishment and/or commencement of activities

Please provide a copy of your CV

Select one premium option only for professional liability coverage purposes:

Projected Annual Gross Fee Income (€)	€250,000 Limit of Indemnity	€500,000 Limit of Indemnity	€1,000,000 Limit of Indemnity	€2,000,000 Limit of Indemnity
€0 - €50,000	€250	€380	€540	€765
€50,001 - €100,000	€350	€525	€720	€1,020
€100,001 - €150,000	€450	€665	€900	€1,275
€150,001 - €200,000	€550	€800	€1,000	€1,530
€200,001 - €250,000	€650	€950	€1,260	€1,785

Select one premium option only for public liability coverage purposes. Please note you can only purchase public liability coverage in conjunction with professional liability, not in isolation.

€1,000,000 Limit of Indemnity	€2,000,000 Limit of Indemnity	€5,000,000 Limit of Indemnity
€100	€200	€300

***Premiums are subject to local tax as applicable.**

Proposed inception date ____ / ____ / ____

DUTY OF FAIR PRESENTATION

It is your duty to make a fair presentation of the risk to the insurer, in accordance with Section 3 of the Insurance Act 2015.

You must:

- a) disclose to the insurer every material circumstance which the proposer knows or ought to know. Failing that, the proposer must give the insurer sufficient information to put a prudent insurer on notice that it needs to make further enquiries in order to reveal material circumstances. A matter is material if it would influence the judgement of a prudent insurer as to whether to accept the risk and, if so on what terms (including premium);
- b) make the disclosure in clause a) above in a reasonably clear and accessible manner; and
- c) ensure that every material representation as to matter of fact is substantially correct, and that every material representation as to matter of expectation or belief is made in good faith.

Failure to do so may prejudice your rights in the event of a claim or result in insurers voiding your policy.

Unless agreed otherwise, failure to make a fair presentation of risk in accordance with the Insurance Act 2015, will provide insurers with the following remedies:

1. If the breach of duty of fair presentation was prior to entering into the insurance contract, the remedies available to the insurer are set out below:
 - a) If the insured's breach of the duty of fair presentation is deliberate or reckless:
 - i) the insurer may avoid the contract, and refuse to pay all claims; and
 - ii) the insurer need not return any of the premiums paid.
 - b) If the insured's breach of the duty of fair presentation is not deliberate or reckless, the insurer's remedy shall depend upon what the insurer would have done if the insured had complied with the duty of fair presentation:
 - i) If the insurer would not have entered into the contract at all, the insurer may avoid the contract and refuse all claims, but must return the premiums paid.
 - ii) If the insurer would have entered into the contract, but on different terms (other than terms relating to the premium), the contract is to be treated as if it had been entered into on those different terms from the outset, if the insurer so requires.
 - iii) In addition, if the insurer would have entered into the contract, but would have charged a higher premium, the insurer may reduce proportionately the amount to be paid on a claim (and, if applicable, the amount already paid on prior claims). In those circumstances, the insurer shall pay only X% of what it would otherwise have been required to pay, where $X = (\text{premium actually charged} / \text{higher premium}) \times 100$.

2. If the breach of duty of fair presentation was prior to entering into a variation to the insurance contract, the remedies available to the insurer are set out below:
 - a) If the insured's breach of the duty of fair presentation is deliberate or reckless:
 - i) the insurer may by notice to the Insured treat the contract as having been terminated from the time when the variation was concluded; and,
 - ii) the insurer need not return any of the premiums paid.
 - b) If the insured's breach of the duty of fair presentation is not deliberate or reckless, the insurer's remedy shall depend upon what the insurer would have done if the insured had complied with the duty of fair presentation:
 - i) If the insurer would not have agreed to the variation at all, the insurer may treat the contract as if the variation was never made, but must in that event return any extra premium paid.
 - ii) If the insurer would have agreed to the variation to the contract, but on different terms (other than terms relating to the premium), the variation is to be treated as if it had been entered into on those different terms, if the insurer so requires.
 - iii) If the insurer would have increased the premium by more than it did or at all, then the insurer may reduce proportionately the amount to be paid on a claim arising out of events after the variation. In those circumstances, the insurer shall pay only X% of what it would otherwise have been required to pay, where $X = (\text{premium actually charged/higher premium}) \times 100$.
 - iv) If the insurer would not have reduced the premium as much as it did or at all, then the insurer may reduce proportionately the amount to be paid on a claim arising out of events after the variation. In those circumstances, the insurer shall pay only X% of what it would otherwise have been required to pay, where $X = (\text{premium actually charged/reduced total premium}) \times 100$.

Proposal form



The quotation is valid for 30 days from the date of the declaration. It is for an annual certificate of insurance for 12 months from the agreed inception date and subject to the conditions stated overleaf.

Declaration

Please confirm all items below and sign the declaration in order to validate this quotation:

- I declare that I have made a fair presentation of the risk, by disclosing all material matters which I know or ought to know or, failing that, by giving the Insurer sufficient information to put a prudent insurer on notice that it needs to make further enquiries in order to reveal material circumstances.
- I confirm I have read the Eligibility Criteria and that all criteria are satisfied
- I confirm that I or my company does not have assets, employees or conduct any work in the U.S.A./Canada
- I confirm I have no other policy in force covering the risks covered by this insurance

TO BE SIGNED BY THE PROPOSER ONLY OR DIRECTOR, PARTNER OR PRINCIPAL OF COMPANY (if applicable)

Signed	
Position	
Dated (dd/mm/yyyy)	

Please send a scanned copy of this proposal by email to Miller at cra@miller-insurance.com or by post to:

Graeme Lynch
Miller Insurance Services LLP
70 Mark Lane
London
EC3R 7NQ

NB: No cover is in force until you have confirmed acceptance and cover has been bound by insurers.

A copy of this proposal form should be retained for your own records.

Important Information

Professional Liability Claims-Made and Notified Insurance:

In respect of professional liability only the certificate, issued by Miller on behalf of The Medical Professional Liability Company Limited (MPLC), contains coverage on a claims-made basis. This means that the certificate only covers *Claims* first made against the *Insured* during the *Certificate Period* and notified to the insurer in writing during the *Certificate Period* in accordance with the *Claims Conditions*.

Public Liability Losses Occurring Insurance:

In respect of public liability only the certificate issued by Miller on behalf of the MPLC contains coverage on a loss occurring basis.

The certificate for both professional liability and public liability does not provide cover for:

- i. any *Claims* made, threatened or intimated against the *Insured* prior to the *Certificate Period*;
- ii. any *Claim* or loss arising out of any *Circumstance* which the *Insured* was aware of or ought reasonably to have been aware of prior to the *Certificate Period*;
- iii. any *Claim*, *Circumstance* or other matter notified to any insurance policy preceding the *Certificate Period*.

Retroactive Date - applicable to Professional Indemnity certificate:

Unless specifically agreed by Insurers no cover shall be provided for any *Claims* arising out of the exercise and conduct of the Professional Business carried out prior to the inception date of the Certificate.

Subrogation:

The certificate contains provisions which have the effect of excluding or limiting the insurer's liability in respect of a *Claim* or loss where you have prejudiced the insurer's rights of subrogation where you are a party to an agreement which excludes or limits insurer's rights of recovery from another party, or where you are found to have committed a criminal act by way of final adjudication or final determination. You are hereby notified of the effect of these provisions.

Jurisdictional and Geographical Limitation:

European Union

Questions or Queries:

If you have any questions or queries regarding the contents of this application and/or you wish to discuss additional coverage requirements please contact cra@miller-insurance.com in the first instance.

Eligibility Criteria

- The proposer must have at least 12 months biomedical Clinical Trial research experience;
- The proposer is domiciled and registered in the European Union and only conducts work within the European Union;
- There are no other business activities undertaken by the proposer other than those listed in the definition of professional business (see below);
- There have not been, nor are there now pending, any *Claims* or losses against the proposer;
- The proposer is not aware, after enquiry, of any *Circumstances* or incident which may give rise to a *Claim* or loss against you in any capacity;
- The proposer is not aware, after enquiry, of any Investigation or prosecution (actual or pending) against you;

Important Information

If you are purchasing the additional Public Liability coverage:

- The proposer does not work with silica, asbestos, or substances containing asbestos, acids, gases, explosives, radioactive, or similar dangerous liquids.
- The proposer does not do any work on power stations, nuclear installations, or establishments, on refineries, bulk storage, or premises in oil gas or chemical industries, or offshore structures, aircraft, hovercraft aerospace systems, watercraft, railways, underground, or underwater.

Definition of Professional Business

- Developing and writing *Clinical Trial* protocols (outlining the purpose and methodology of a *Clinical Trial*);
- Presenting *Clinical Trial* protocols to a steering committee;
- Designing data collection forms, known as Case Record Forms (CRFs);
- Co-ordinating with the Ethics Committee, which safeguards the rights, safety and wellbeing of all *Clinical Trial* subjects;
- Managing regulatory authority applications and approvals (that oversee the research and marketing of new and existing drugs);
- Locating and assessing the suitability of facilities at a study centre;
- Briefing doctors/consultants (or investigators) on conducting the *Clinical Trial*;
- Setting up the study centres, which includes ensuring each centre has the *Clinical Trial* materials and training site staff to *Clinical Trial* specific and industry standards;
- Monitoring the *Clinical Trial* throughout its duration, which will involve visiting the study centres on a regular basis;

- Auditing clinical trial procedures including regulatory affairs and good clinical practice.
- Verifying that data entered on to the CRFs is consistent with patient clinical notes, known as Source Data/Document Verification (SDV);
- Collecting completed CRFs from hospitals and General Practices;
- Writing visit reports;
- Filing and collating *Clinical Trial* documentation and reports;
- Ensuring all unused *Clinical Trial* supplies are accounted for;
- Closing down study centres on completion of the *Clinical Trial*;
- Discussing results with a medical statistician, who usually writes technical
- *Clinical Trial* reports;
- Archiving study documentation and correspondence;
- Preparing final reports and occasionally manuscripts for publication;
- Project management.

Excess:

- Professional liability - a €1,000 excess applies to each and every claimant including costs and expenses
- Public liability - a €250 excess applies to each and every claimant including costs and expenses

Indemnity Limit:

Aggregate including Costs and expenses

Special Note:

Where *italicised* words are used, please refer to certificate documentation as these are defined terms.



The Medical Professional Liability Company Limited.
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MPLC have granted Miller Insurance Services LLP authority to process applications, issue certificates and process premiums and claims under this scheme.