

What is this type of Insurance?

Clinical Trials Insurance



What is insured?

- ✓ Clinical Trials policies provide indemnity to the Named Insured for their legal liability to pay compensation in respect of injury to a research subject arising out of their participation in a clinical trial.
- ✓ Coverage applies based on the agreed protocol that describes the objectives, design, methodology, statistical considerations and organisation of a Clinical Trial.



What is not insured?

- ✗ Departure from Protocol
- ✗ Trials that have not been granted Ethics Committee and/or Licencing Authority approval.
- ✗ Failure of Intended Medicinal Purpose
- ✗ Intended or expected Injury
- ✗ Persons employed



Are there any restrictions on cover?

- ! Continued use of Medicinal Products
- ! Contractual Liability
- ! North America
- ! Pre-existing conditions



Where am I covered?

- ✓ Protocol dependant/Worldwide.
- ✓ Master policy subject to the laws and jurisdiction of Sweden. Local Policies subject to local law.



What are my obligations?

- The Named Insured shall take all reasonable precautions to prevent accidents and prevent or cease any activity which may give rise to legal liability and shall take all reasonable steps to comply with all statutory or local obligations and requirements.
- If the premium due under this Policy has not been so paid to the Company by the 60th day from the inception of this Policy (or within 60 days of local policy documents being issued, whichever is sooner) the Company shall have the right to cancel this Policy by notifying the Insured in writing direct or via the broker or agent as appropriate. In the event of cover being cancelled, prior to enrolling any patients into the trial, a cancellation fee of EUR 1,000 for each territory in which cover was bound, will be charged. The full policy premium shall be payable in the event of a loss or occurrence prior to the date of termination which gives rise to a valid claim under this Policy.
- In the event of a claim, the Named Insured or any party claiming indemnity under the policy shall give written notice to the Company with full details as soon as reasonably practicable, shall make no admission of liability or offer or promise of payment without the Company's written consent, shall inform the Company of any impending prosecution, inquest, fatality or civil proceedings and shall produce any books of accounts or other business documents as may be reasonably be required by the Company for investigating or verifying a claim.



When and how do I pay?

- The Named Insured undertakes that premium shall be paid in full to the Company within 60 days from inception.
- Premiums can be paid either centrally or locally if required by local laws and regulations. This will be dependent on where your trials are being undertaken and detailed in your quotation documents.
- Premium payment is made by means of a bank transfer as per the details attached in your invoices in the currencies noted in the invoices.



When does the cover start and end?

Cover remains in place for the duration of the clinical trial (life of trial).



How do I cancel the contract?

In the event of cover being cancelled, prior to any patients being enrolled, a minimum premium of EUR 1,000 for each territory in which cover has been bound, will be charged.