Clinical Trials Lux En

Insurance Product Information Document

Company: Zurich Insurance Europe AG, Belgian branch, non-life insurer, authorised by the FSMA under number 2079 (BEL).

Product: Clinical Trials Lux En

This document provides a summary of the main coverages and exclusions. Full details are contained in the general and specific policy conditions.

What is this type of insurance?

This is a strict liability insurance (i.e. liability without fault) intended to cover the civil liability of the sponsor and/or investigator of a clinical trial for bodily injury and property damage suffered by participants in the clinical trial (and/or their beneficiaries), even in the absence of fault, directly resulting from participation in a specifically defined clinical trial (protocol), in accordance with Luxembourg legislation on clinical trials.

What is insured?

- ✓ Bodily injury suffered by clinical trial participants, including death, illness or disability
- ✓ Property damage
- ✓ Financial losses consequential upon covered bodily injury or property damage
- ✓ Defence costs of the insured persons

What is not insured?

- ✗ Fines and criminal or administrative penalties
- ✗ Fraudulent, intentional or criminal acts
- ✗ Avoidable or repetitive damage
- ✗ Gross negligence
- ✗ Consequences of war
- ✗ Employer's liability
- ✗ Professional liability of healthcare providers
- ✗ Non-consequential financial losses and financial losses consequent upon non-covered bodily injury or property damage
- ✗ Damage resulting from a deliberate deviation from the protocol or lack of informed consent
- ✗ Ineffectiveness of the medical product tested within the clinical trial
- ✗ Damage related to continued use of a medical product after the end of the trial
- ✗ Genetic damage
- ✗ Aggravation of pre-existing medical conditions
- ✗ Failure of a placebo

Are there any restrictions on cover?

- ! Coverage is limited to one specific protocol per policy
- ! The limit of indemnity is as stated in the policy
- ! The deductible is as stated in the policy
- ! Coverage is triggered by the submission of a claim to the policyholder or directly to the insurer

Where am I covered?

- ✓ Coverage applies to investigation sites located in Luxembourg where the clinical trial is conducted.

What are my obligations?

- If you apply for the insurance, you must answer our questions honestly. You must do as much as possible to prevent and limit damage. You must report damage as soon as possible. You must notify us of important changes in your business as soon as possible.

When and how do I pay?

- You pay the premium via a premium payment request that you receive from your intermediary or advisor. You must pay the premium within 30 days of the invoice date, unless otherwise agreed. The premium payment request states where you must transfer the amount.

When does the cover start and end?

- The insurance policy takes effect on the date specified in the policy and remains in force for the entire duration of the clinical trial.

How do I cancel the contract?

- The policy may be terminated before the start of the clinical trial, provided that no claim has been reported. Once participants have been enrolled in the clinical trial, the policy can no longer be terminated.