

CHUBB®

Clinical Trials Insurance

At Chubb, we recognise that clinical trials are pivotal to advancing the life sciences industry, and understand the complex risks inherent in these operations.

That's why our Clinical Trials Insurance is designed to provide your company with comprehensive coverage for liabilities, including no-fault compensation and legal liability. Whether you're conducting single clinical trials or large multinational trial programs, our coverage addresses risks arising from clinical trials conducted locally or overseas, as well as across all participant, disease and product types.

Coverage highlights

Key benefits

Our clinical trials policy covers your activities for these areas:

- Clinical trial liability in all trial phases
- Liability for injury to a research subject, including no-fault compensation
- Single clinical trials through to blanket programs
- Domestic and multinational clinical trials
- Drug or medical device testing, including implantable devices and vaccines
- Indemnity extended to clinical research organisations and ethics committees



Clinical Trials Extras

Additional covers for events involving injured research subjects, including:

- Product recall expenses
- Crisis response expenses
- Medical monitoring of uninjured subjects
- Expenses and liabilities arising from a privacy breach
- Legal costs to attend coronial or regulatory inquiries

WORLDcert™

Chubb's interactive clinical trial insurance system simplifies securing coverage by providing:

- Instant issuance of quotes and certificates*
- Key insurance information and requirements at country level

*Instant certificate issuance available in 34 countries.

^ includes automatic period.

Extended Liability and Reporting Periods

- Automatic extended reporting periods per local regulations
- Optional Extended Reporting Period up to total 10 years^
- Extended liability cover for future claims related to claims / incidents notified during the policy period.

Who we insure

Chubb's insurance offerings for clinical trials covers businesses, institutions and professionals including:

- Biotechnology businesses
- Pharmaceutical manufacturers
- Medical device manufacturers
- Hospitals
- Universities and colleges
- Research institutes
- Physician groups



The benefit(s) payable under eligible certificate/policy/product is(are) protected by PIDM up to limits. Please refer to [PIDM's TIPS brochure](#) or contact [Chubb Insurance Malaysia Berhad](#) or PIDM (visit www.pidm.gov.my)

Clinical trials claims scenarios



European trial claim affects multiple policies

A clinical trial participant in Europe won a EUR2,200,000 settlement for bodily injury sustained in the trial. As the compulsory insurance cap per participant in the country where it occurred is only EUR450,000, a significant portion of the settlement exceeded the coverage limit of the local policy. However, the master trial policy included a difference in limits (DIL) provision allowing the full claim to be paid by combining the local and master policies.

Potential Cost: EUR 2.2M



Failure to fully disclose bodily injury risks

The plaintiff experienced liver toxicity after participating in a clinical trial for a new drug. He alleged the pharmaceutical manufacturer did not fully disclose the risks of the study drug in the informed consent document. While there was a general warning of potential adverse effects, this specific effect was not addressed, despite some animal studies showing the potential for liver toxicity.

Potential Cost: USD 1.3M



Clinical trial patients suffer immune disease

Two participants developed an immune disease during a trial to test a new drug for a genetic blood disorder. The immune disease required an expensive monoclonal antibody therapy. The parties reached an agreement in accordance with the Trial Compensation Protocol for the participants to receive payment for reasonable medical expenses and compensation for pain and suffering, as well as the costs of the monoclonal antibody therapy.

Potential Cost: USD 2.1M



Clinical trial patient suffers nerve damage

Whilst participating in a Phase I safety and toxicity study, a healthy volunteer developed facial nerve damage after receiving the pharmaceutical company's investigational drug. This resulted in the volunteer seeking compensation from the pharmaceutical company testing the drug.

Potential Cost: USD 175,000

Why choose Chubb?



Specialist Expertise

20 years' experience in Asia Pacific delivering expertise in underwriting, claims and risk engineering to life sciences businesses.



Claims Service

Chubb's award-winning claims team is consistently acknowledged as one of the best in the market.



Global Services

Offering global services across 54 countries and territories, from compulsory insurance for clinical trials to local liability policies.

Find the right insurance solution for your life sciences business: www.chubb.com

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