

United Kingdom Clinical Trials

- This guide is for intermediary reference only.
- This guide does not contain the full terms and conditions of the contract of insurance which can be provided.

Carrier name: Allianz Global Corporate & Specialty SE (AGCS)

Broker name: N/A

Product name: UK Clinical Trials

Reference: NA

Class of Business: Liability

MANUFACTURER INFORMATION

Product Design

AGCS has been providing Clinical Trials insurance around the world for over 15 years and work with industry experts across the Allianz Group. We continually draw upon this experience and insight to ensure this product continues to add value and meet the needs of Clinical Trial clients.

This Clinical Trials Insurance product can be offered to customers domiciled all over the world who might conduct Clinical Trials in the United Kingdom. The product is designed following the guidelines issued by local regulators and to meet the strict requirements needed for trial approvals. In the United Kingdom the guidelines are issued by the **Association of British Pharmaceutical Industry (ABPI)**. Policies must comply with the principles set out by the ABPI and are usually issued on a duration of trial basis. The average Clinical Trial lasts between 4/5 years but some policies can run for over 10 years.

Target Market

Clinical Trials are conducted or sponsored by a wide range of organisations, including: pharmaceutical and biotechnology companies, institutions such as universities and hospitals; private research organisations, publicly funded research organisations, Contract Research organisations and medical device companies.

The sponsor is the entity or person that initiates, organises and supports the clinical trial and takes responsibility for the overall conduct of the trial, including liability for injuries that may be suffered by patients. This product would be unsuitable to customers who are conducting Clinical Trials outside the UK.

Any notable exclusions or circumstances where the product will not respond

- Persons Employed - Injury to an Employee unless such Employee is a Research Subject in the Clinical Trial.
- Contractual Liability of others assumed by the Insured under the terms of an agreement but liability under the Compensation Agreement
- Failure to obtain Approvals and Authorizations
- Failure of Intended Medicinal Purpose
- Departure from Protocol
- Failure to obtain Informed Consent
- Continued use of Medicinal Product
- Pre-existing medical conditions
- Intended or Expected Injury

Other information which may be relevant to distributors including product value assessment and distribution strategy

- This product is sold in the UK by AGCS and all claims and complaints are handled by AGCS
- The AGCS product value assessment concluded that this UK Clinical Trials insurance, including its charging and distribution structure is compatible with the needs, objectives and characteristics of the target market and provides fair value
- The AGCS product value assessment is based on the premium we charge for the cover and the services AGCS provide. Also considered are a wide number of factors such as historical and expected claims frequencies, incurred and projected claims costs as well the global long tail nature of the exposure of AGCS to liabilities with Clinical Trials around the world and not exclusive to UK exposure only.
- This policy can be offered as a one-off standalone cover or as part of a wider cover for a customer with multiple clinical trials
- Endorsements to policies can be normal for this product due to the length of time of cover over the course of the Clinical Trial or multiple trials and changes that need to be made to ensure appropriate cover
- Clinical Trials insurance for UK trials is distributed solely by brokers in the United Kingdom who should have the appropriate level of understanding of the risks and exposures faced by their customer in the operation of their business when carrying out Clinical Trials

- The level of commission is in line with market proximate commission levels and is not increased from what AGCS has agreed with the placing broker for the policy
- Fees are not charged as standard nor any profit sharing

Product value assessment completed:

UK Clinical Trials 13 December 2023

Expected date of next assessment:

December 2024