

华泰财险附加临床试验扩展条款（索赔发生制）

根据本保险条款的承保条件，保险人将负责赔偿被保险人在实施临床试验过程中对临床试验受试者造成“人身损害”，受试者因而向被保险人提出“索赔”，依据临床试验所在地国家的相关法律法规被保险人应当承担的赔偿责任。但该“人身损害”应当在保险单列明的追溯日至保险期间届满之日的期间内发生，且“索赔”是在保险期间内首次向被保险人提出，并于在保险期间内或任何适用的延长报告期之内报告给保险人的。

但该等损失和责任不是由于被保险人的主要研究人员和/或参与研究的机构及其服务人员或代理人的严重违反临床试验方案或疏忽行为造成的。

释义：

“**临床试验**”是指：

- (1) 使用由被保险人或代表被保险人生产、准备的任何物质而实施的临床测试；
- (2) 由被保险人实施或在被保险人指导下对第三方生产或准备的物质进行临床测试或试验；
- (3) 在进行以上的临床测试或试验过程中提供的医疗服务。

由临床试验导致的“人身损害”应被视为是由被保险人提供的产品所造成的。

医疗服务是指由被保险人或代表被保险人提供或者应该提供的任何医疗性质的服务，包括以下内容：

- (1) 内科、手术、牙科、护理或兽医方面的治疗或服务，包括与其相关的而提供的食品或饮品；
- (2) 提供或配制药剂或内科、牙科、手术或兽医方面的相关用品或器具；
- (3) 处理或进行人体或动物的尸检。

但不包括有以下原因引起的责任：

- (1) 对被保险人的雇员作为受试志愿者进行临床试验；
- (2) 试验研究者、机构或其服务人员或代理人的疏忽。

K68 Clinical Trial Liability (Claims Made)

The Company will indemnify the Insured for the legal liability as a result of a “**Claim**” that arises from “**Bodily Injury**” to Clinical Trial test subjects under the terms of this Policy in accordance with any applicable national guidelines or any provisions provided for under local legislation concerning the conduct of Clinical Trials, provided that such “**Bodily Injury**” did not occur before the Retroactive Date or after the Policy Period set forth in the Policy Schedule, and the “**Claim**” is first made against the Insured during the Policy Period and reported to the Insurer during the Policy Period or any applicable extended reporting period .

Also provided that such indemnity will not apply to claims or losses arising out

of any significant breach of protocol for the Clinical Trials, or to any act of negligence by the principal investigator and/or the institutions which participate in the study or their servants or agents.

Definitions:

“Clinical Trials” shall mean

(1) the clinical testing of any substance manufactured or prepared by or on behalf of the Insured

(2) any clinical testing or trial conducted by or at the direction of the Insured on any substance for others

(3) Medical Services during the course of such clinical testing or trials

Bodily Injury arising out of Clinical Trials shall be deemed to have been caused by Products supplied.

Medical Services shall mean any service of a medical nature rendered, or which should have been rendered, by or on behalf of the insured including any of the following:

(1) medical, surgical, dental, nursing or veterinary treatment or services, including the furnishing of food or beverages in connection therewith

(2) furnishing or dispensing of drugs or medical, dental, surgical or veterinary supplies and/or applicants

(3) handling of or performing post mortem examinations on human or animal bodies

Excluding liability arising out of

(1) Clinical Trials conducted on volunteers in the employment of the Insured

(2) The negligence of the investigator, institution or their servants or agents.