

Overview of the clinical trials insurance

Legal facts

In Germany, the Medicinal Products Law (AMG), the Medical Devices Law (MPG), the Atomic Energy Law (ATG), the Radiation Protection Law (StrVG), the supplementary liability insurance for the approved use of radioactive materials or ionizing radiation on humans (AVB Strl-Zusatz-HV) or the X-ray Regulation (RöV), regulate for example the following liability obligations for subjects in clinical trials: protection of humans + liability for claims on the product to be tested + extended liability. In the EU- and EWR countries and especially globally the laws and regulations are not uniformly regulated, considerable differences exist.

Who is insured and for how long?

- Insured are test persons as well as their unborn children during the entire period of the clinical trial as well as during the extended liability period.
- The insurance cover starts with the initial examination of the test person, at the latest with his written consent to participate in the study. The clinical trial ends with the final examination of the test person.
- In addition, insurance coverage for health injuries to test persons is extended to a maximum of 5 years after completion of the study. For long-term studies or radiotherapy, significantly longer extended liability periods (up to 30 years) apply.

What does the insurance cover?

Example: the test product unexpectedly caused health damage to the test person.

- The insurer compensates the material damage incurred. Necessary medical treatment costs, future financial losses, but also reasonable burial costs, will also be reimbursed.
- The insurance sum for each test person amounts up to € 500,000. This varies depending on the country in which the clinical trial takes place (up to € 1 million).
- Compensation for immaterial damages is excluded.
- Not all parties involved in the clinical trial are covered by the clinical trials insurance. For example financial losses caused by directors and officers (D&O-directors and officers liability insurance) or commuting accidents are excluded.

What must be done in case of amendments or in assumed or occurred health problems?

If any changes occur, unexpected side effects or a health damage are suspected, the insurer must be informed immediately.

The commuting accident and D&O Insurance

The commuting accident or D&O insurance is explicitly recommended. Legal disputes often arise, for example, when accidents happen on the way to and from the medical control investigation, or directors and officers cause financial liability losses in their company.