NO-FAULT COMPENSATION FOR CLINICAL TRIALS AND/OR HEALTHY VOLUNTEER STUDIES

DEFINITIONS

INSURED
The Institution or company sponsoring or performing the Clinical Trials, whose name is indicated in the Policy and in the Certificate of Insurance.
If the Insured named in the Policy and in the Certificate of Insurance only sponsors such trial, but the said trial is performed by other medical institution(s), for the purpose of this insurance the employees of the institution(s): investigator and his/her assistant medical staff, consultants and persons providing medical services, performing and controlling the said trial, shall be deemed to be co-insureds if medical institution(s) is named in the Policy and in the Certificate of Insurance.

TRIAL SUBJECT
An individual patient or non-patient volunteer who after signing the Informed Consent participates in the clinical trial.

CLINICAL TRIAL / STUDY
Any investigation being performed on human subjects, whether patients or non-patient volunteers, intended to discover or verify the clinical pharmacological and/or other pharmacodynamic effects of an investigational medicinal product and/or to identify any adverse reaction to an investigational medicinal product and/or to study absorption, distribution, metabolism and excretion of an investigational medicinal product with the object of ascertaining its efficacy and safety.

INVESTIGATIONAL MEDICINAL PRODUCT
A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorization but used or assembled (formulated or packaged) in a way different from the authorized form, or when used for an unauthorized indication, or when used to gain further information about the authorized form.

The trial should comply with the following requirements:

1. the statutory requirements of the country where the Trial or Study takes place, and
2. the guidelines being in force applicable to the Trial or Study, prescribed by the ministries and state bodies dealing with health or medical research, or of the body representing the pharmaceutical manufacturers in the country where such trials took place, and
3. the Trial or Study should possess the approval from the relevant research ethics committee and also the permit of the authority registering the substance under trial, provided that it is necessary on the basis of points 1 or 2 above.
I. RISK INSURED AND SCOPE OF INSURANCE

The Insurer shall cover the legal liability of the Insured in respect of losses caused to the Trial Subject in the course of the clinical trial named in the Policy and in the Certificate of Insurance performed or sponsored by the Insured, for which the Insured is liable and obliged to pay compensation according to the rules of the Civil Code of Hungary.

In the absence of negligence of the Insured, coverage is granted within the scope of legal liability to the same extent which would be imposed on the Insured if he became legally liable as a result of negligent acts or omissions.

II. INSURED EVENT

Death or injury to health of the Trial Subject caused directly as a result of:
   a) application of the investigational medicinal product under trial.
   b) the professional duties being performed by those persons (named under "Insured") in connection with the insured clinical trials

III. TERRITORIAL AND TIME SCOPE OF INSURANCE

TERRITORIAL SCOPE

On the basis of this insurance contract, the Insurer shall indemnify for losses caused within the territorial limits stated in the Insurance Policy.

TIME SCOPE (PERIOD OF INSURANCE)

The insurance contract shall be concluded for the time of duration of the clinical trial specified in the policy. In absence of any agreement to the contrary, provided that the contract has been concluded, the insurance shall come into force as of the day following the day when the Policyholder paid the first premium to the account of the Insurer, or when the parties agreed on delayed premium payment, or when the Insurer enforces its claim towards the premium through court procedure.

If the parties agreed on the commencement of this insurance (the contract period) at a later date, the liability of the Insurer commences earliest at such date, irrespective of the fact that the proposal has been received earlier. In this case, however, the premium paid should be accounted for such a period that does not commences earlier than the effective date of this insurance (the contract period).

The insurance covers insured events, which have occurred during the period of insurance or after its termination, but not later than within five years following the conclusion of the clinical trial. In case of doubts it shall be assumed that date of insured event occurrence is date of first medical examination of injury caused by participation in a clinical trial.

IV. INSURANCE BENEFITS

If an insurance event occurs the benefits provided by the Insurer shall cover the following:

1. compensation for the death or injury to health in accordance with the applicable civil code regulations;
2. costs of litigation and legal defence approved by the Insurer in advance. Such approval will not be unreasonably withheld or delayed.

V. EVENTS AND LOSSES NOT COVERED BY THIS INSURANCE

The indemnification obligation under this insurance shall not cover the following:
1. any claims arising from circumstance(s) or occurrence(s) which has been notified under any Policy or Certificate of Insurance attaching prior to the inception of this Policy;

2. claims on the account of injuries inflicted on purpose;

3. claims arising from the fact that the investigational medicinal product did not meet the expectations or did not produce the expected beneficial results;

4. injuries, the occurrence of which is highly probable owing to the nature of the conducted clinical trial, or which do not exceed the acceptable degree according to the present state of medical knowledge;

5. claims arising out of addiction caused by investigational medicinal product if such possibility was known;

6. injuries, which would have occurred even in the case of not participating in the clinical trials;

7. in the cases when the study includes the trial (testing) of an investigational medical product, no indemnification is paid to the Trial Subject who did not receive such a medical product during the trial, except
   a) if the loss arises from the fact that in the interest of the trial, other medical products or treatments that otherwise would be used for the mitigation of the given illness or condition, were withheld, or
   b) if the placebo having been given to the Trial Subject makes the refusal of the indemnification to be unreasonable;

8. claims directly or indirectly caused by or contributed to by or arising from ionising radiation or radioactive contamination by radioactivity from any nuclear fuel or any nuclear waste from the combustion of any nuclear fuel; or from the radioactive, toxic, explosive or other hazardous properties of any explosive nuclear assembly or nuclear component thereof;

9. claims arising out of participation of pregnant women;

10. injuries resulting from genetic changes;

11. any claim or claims or legal proceeding instituted
    a) within the United States of America or Canada, or any other territories that come within the jurisdiction of the United States of America or Canada,
    b) to enforce a judgement obtained in any court of the United States of America or Canada, or any territories which come within the jurisdiction of the United States of America or Canada;

12. any liability losses that arise not from a legal rule but from a contract and exceeding the prevailing legal liability;

13. fines and penalties determined by courts or authorities;

14. any losses caused by or in consequence of:
    a) war, invasion, acts of foreign enemies, hostilities or warlike events (whether war be declared or not), civil war,
    b) permanent or temporary seizure, resulting from confiscation, military appropriation or requisition on the order of a legal authority,
    c) riot, strike, rebellion, separatist action, military or civil appraisal, insurrection, counterrevolution, revolution, military or usurped power, martial law or any other event or reason the declaration of which entails the introduction of martial law,
    d) terrorist action committed by any organisation or any person or persons acting on behalf or in connection with such organisations.
    (For the purpose of this exclusion “terrorism” shall mean any violent action with political goals, and any violent action aimed at putting the whole or a part of the population under terror.)
VI. LOSSES NOT COVERED BY THIS INSURANCE BECAUSE OF THE INSURED’S / POLICYHOLDER’S BREACH OF CONTRACT

1. The liability of the Insurer shall not arise if the Insured (the Policyholder) failed to comply with his/her reporting obligation outlined in Section IX, and therefore substantial circumstances became concealed.

2. In the case of breach of the reporting and change reporting obligation determined in Section VIII, the liability of the Insurer shall not arise, unless it is proved that the circumstance so concealed or not reported was known to the Insurer at the conclusion of the contract or they did not interfere with the occurrence of the insurance event.

VII. RULES OF DATA DELIVERY AND PREMIUM PAYMENT

1. The premium for this insurance shall be determined as a function of the premium base, in proportion with the risk exposure.

2. The premium basis of this insurance shall be determined taking the following into consideration:
   a) the limit of indemnity (limit of indemnification per event and in the aggregate),
   b) the investigational medicinal product,
   c) number of patients or non-patient volunteers involved,
   d) period of the trial and period regarding one patient or non-patient volunteer,
   e) the phase of the trial performed or sponsored by the Insured,
   f) the deductible chosen by the Insured (Policyholder) and
   g) the territorial scope.

3. The Insured shall provide the Insurer with all data necessary for the determination of the premium at the conclusion of the contract on the Schedule signed for and on behalf of the Insured, and forming an integral part of the insurance proposal.

VIII. REPORTING AND CHANGE REPORTING OBLIGATION OF THE INSURED

1. At the conclusion of the contract the Insured shall be obliged to inform the Insurer on all circumstances that are relevant from the underwriting aspect and that were or should have been known to him. This obligation will be met by the Insured by giving true answers to the questions raised by the Insurer in writing.

2. The Parties agree that in the course of the contract period the Insured complies with the said reporting obligation in such a way that he/she reports any changes to the circumstances prevailing at the date of contract conclusion within 8 working days to the Insurer, in writing.

3. If the Insurer gains knowledge on circumstances that are relevant from the aspect of the contract only after the contract conclusion, or it is provided with information regarding material changes, it may propose the amendment of the contract within 15 days, or - if according to the prevailing regulation the risk cannot be accepted, it may cancel the contract with a 30 days notice.
   If the Insured does not agree on the proposed amendments or does not respond within 15 days, the contract is terminated on the 30th day from the day when such proposal was made. The Insured should be informed on the above consequence simultaneously with the said proposal.
   Should the Insurer not exercise its above mentioned right, the contract will remain in force with the original contents.

4. Any changes in the legal status of the Insured (e.g. separation, merger, cessation) should be reported to the Insurer within 8 working days.
IX. OBLIGATIONS OF THE INSURED FOLLOWING THE OCCURRENCE OF THE INSURANCE EVENT

1. Following an insurance event or a claim made against him/her, the Insured shall be obliged to report same in writing without delay after its coming to his/her knowledge, to the unit of the Insurer handling the insurance contract.

2. The loss report should include the following:
   - a) description and date of the loss event,
   - b) name of the investigational medicinal product causing the loss,
   - c) name of the medical institution and the investigator controlling the trial,
   - d) degree of the loss (stated or estimated value) - name and data of the persons injured and the degree of the injury,
   - e) name, address and telephone number of the person designated by the Insured to participate in the loss adjustment.

3. If there was any litigation in respect of the loss event, the Insured shall be obliged to present the relevant resolution to the Insurer.

4. On the request of the Insured the Insurer shall represent the Insured in and outside of the civil procedure. In this case the costs of such representation shall be borne by the Insurer, however subject to the provisions of X section 1.
   The Insured shall not admit any claim or make any compromise or pay any indemnification without the consent of the Insurer. Such commitment assumed or payment made by the Insured shall not be binding for the Insurer.
   Any condemnation made against the Insured in a civil procedure initiated by the claimant shall be binding for the Insurer in that case only if the legal representation was ensured by the Insurer, or it participated in the trial otherwise, or abandoned the representation or participation in the trial.

X. SUM INSURED

1. The sum insured shown in the policy is the maximum amount payable by the Insurer in respect of any loss covered under this policy, including compensation, investigation, adjustment, appraisal and legal costs.

2. The total value of the indemnity compensation contributions provided by the Insurer per one Trial Subject of clinical trial cannot exceed the sum per one Trial Subject guaranteed by the insurance contract, also in the case when there are several beneficiaries.

3. The total value of the indemnity compensation amounts provided by the Insurer on the account of a single clinical trial cannot exceed the sum per single clinical trial guaranteed by the insurance contract.

XI. RULES OF COMPENSATION AND AMOUNT OF INDEMNIFICATION

1. The Insurer shall indemnify for losses - net of deductible - up to the limit amount for any one event and for the aggregate (limit of indemnity) stated in the Policy forming part of the contract.

2. The compensation shall be paid as a lump sum indemnification.

3. The amount of compensation payable shall be appropriate to the nature, severity and persistence of the injury. It should be assessed with reference to the measure and quantum of damages that would have been awarded by the courts of the country where Trial took place at the date on which the compensation is assessed for a substantially similar injury.

4. Compensation shall not be denied or abated by reason of any participation of a third party in causing the damage for which such third party can be made liable (joint liability), but following the settlement of the claim the Trial Subject’s rights against such third party shall be subrogated to the Insurer.
5. The amount of the indemnification shall be paid by the Insurer to the Trial Subject within sixty days from the receipt of all data, deed, expertise and documentation proving the occurrence and the amount of the loss. In connection with any claims against the Insured, the Insurer may at any time pay the Insured the amount equalling the Limit of Indemnity or any lesser amount for which such claims can be settled and thereupon the Insurer shall relinquish the control of such claims and be under no further liability in connection therewith except for the costs and expenses that the Insurer has already agreed to bear in respect of matters, prior to the date of such payment.

XII. DEDUCTIBLE

From the amount of compensation determined for each and every loss occurrence the Insured shall bear the amount of the deductible determined in the contract (policy).

XIII. RECOVERY RIGHTS OF THE INSURER

1. The Insurer may request the reimbursement of the amount of compensation from the Insured (the Policyholder) if the loss was caused by the illegal, deliberate or grossly negligent action of the Insured.

2. For the purpose of this insurance gross negligence shall be if the Insured or his/her employee
   a) performed any activity bound to official licence without such licence
   b) performed his/her activity in absence of the personal and material conditions prescribed by the relevant legal rules or other requirements,
   c) caused the loss in drunken state or under the influence of stupefacient agents, or in consequence of such state, or
   d) the loss was the consequence of the material or repeated breach of the loss prevention, loss mitigation prescriptions or the professional regulations.

XIV. LOSS PREVENTION AND LOSS MITIGATION OBLIGATION OF THE INSURED

1. The Insured shall be obliged to act with due diligence in order to prevent, eliminate or mitigate losses and fully observe the relevant prescriptions at all times.

2. The Insurer itself or its representative shall be entitled to supervise the execution of the loss prevention measures.

3. If the Insurer gained knowledge on the material breach of the loss prevention rules or repeated failure to comply with same, it may initiate immediate amendment of the contract.

XV. MISCELLANEOUS STIPULATIONS

1. Any claim arising from this insurance contract shall lapse after five years from its due date.

2. On the basis of the legal allowance of the Insurer, the Insured is obliged to deliver all evidence and information necessary for the enforcement of the recovery right of the Insurer. Any disadvantages arising from the breach of this obligation shall be borne by the Insured.

3. The Policyholder or the Insured and the Insurer are obliged to make any declaration in writing (via letter or telefax).

4. The Insurer shall be entitled to inspect the risk exposure and the accuracy of the data submitted by the Insured any time on the spot.
5. Any debate between the Insurer and the Insured (Policyholder) in respect of the interpretation of this policy, its validity or the conditions, prescriptions, limits and/or exclusions described in the policy shall be governed by the Law of Hungary.