

Insurance Policy for Clinical Trials

Carlo Tomino Pharm.D.

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AIFA



Ministry of Labour, of Health and Social Policies

“Minimum requirement for the insurance policies to protect participants to clinical trials for medicine”

**Ministry of Employment, of Health and Welfare with
Ministry of Economic Development**



Article 1.

- The sponsor of the clinical trial shall submit to the Ethics Committee an insurance certificate **in Italian**, duly executed by the insurance company under a valid insurance policy, as per the attached standard form which forms an integral part of this decree, which is to make explicit reference to the proposed interventional study and describe its essential aspects as provided by this decree.



Article 1.

- When giving its opinion, the Ethics Committee shall consider the insurance certificate submitted by the sponsor of the clinical trial, as drafted in compliance with the requirements set forth in this decree.

Article 1

- The insurance policy is to grant specific cover in connection with the reimbursement of damages caused to the subjects by the clinical trial activities throughout the entire duration thereof, thus covering any civil liability of investigator and sponsor of the clinical trial, without excluding any damage which may be unintentionally caused by accident and/or be attributed to negligence, imprudence or inexperience.



Article 1

- If the term of validity of the certificate is shorter than the actual term of the trial, sponsor has to submit to the Ethics Committee the relevant renewal certificate upon and by the scheduled expiry date thereof. The submission of the renewal certificate to the Ethics Committee / Competent Authority is a non-substantial amendment.



Article 1.

- Terms set forth in the insurance policy in connection with the outbreak of damages and with the submission of claims may not be respectively shorter than 24 and 36 months from completion of the clinical trial.
- Completion of the clinical trial shall mean the last medical-surgical, diagnostic and/or therapeutic service performed in accordance with the trial protocol applying to the last patient enrolled in Italy.



Article 1.

- In case of trials which are potentially eligible to cause damages which may show after longer periods of time, the minimum period of tail coverage for the risk shall be extended accordingly.
- As regards clinical trials on children, such extension is to contemplate a coverage of at least 10 years, this being the minimum time required to ascertain their regular psychophysical development.



Article 1.

- Clinical trials which involve gene therapy, cellular therapy and radio-pharmaceutical shall require a minimum extended tail coverage for the risk of at least 10 years.



Article 1.

•In any case, the investigator is always required to inform the participants to the trial protocol, even through the informed consent, that the insurance policy covering damages caused by civil liability (as third part liability) in the trial will not cover any amount exceeding its limit of liability and that such policy exclusively applies to damages for which a claim was submitted within and not later than the period provided in the policy and defined in accordance with the criteria hereunder. This restriction shall not in any event impair the right of the damaged party to seek reimbursement of damages from the person liable therefor.





Article 2.

- Insurance shall cover death, all permanent and/or temporary impairment of health conditions, relevant financial consequential losses which are the direct consequence of the trial and which can be traced to the liability of all people operating for the performance of the trial.

Article 2.

•Insurance shall provide for an insured limit for the reimbursement of damages not lower than Euro 1 million per participant, although the following minimum limits for each individual protocol are required, not less than:

- a) Euro 5 million if trial participants are less than or equal to 50
- b) Euro 7 million five hundred thousand if the trial participants are more than 50 but less than 200;
- c) Euro 10 million if the trial participants are more than 200.

Trial participants shall mean the number of patients which take part in the trial in Italy.



Article 2.

- No deductible enforceable against third parties who claim damages may be provided; if the insurance company wishes to terminate the contract, it shall in any case grant the cover to participants. Participants who will be enrolled in the clinical trial after termination by the insurance company, the sponsor shall execute a new insurance policy with another insurance company before enrolling them.
- The amounts of the limits of liability are subject to review every three years.





Article 3.

- Sponsors of no-profit clinical trials shall be under an obligation to extend their own insurance cover as executed in connection with the healthcare activities performed in their organization or execute an additional policy granting specific cover for the civil liability arising from clinical trial activities, in accordance with the minimum requirements provided in this decree.



Article 3.

- In case of multicentre no-commercial trials, each centre involved may refer to its own insurance policy to cover participants from its centre; this being the case, the competent Ethics Committee of each centre shall assess that an appropriate insurance cover is in place for its centre.



Article 4.

- This obligations shall not apply to non-interventional trials (or observational studies).



Article 5.

- Results of trials which do not satisfy the minimum requirements set forth in this decree will not be taken into account for the purpose of evaluating the marketing authorization application.



Article 5.

- Any favourable opinions by the Ethics Committees shall be null and void, together with the relevant authorizations, concerning clinical trials which do not satisfy the minimum requirements set forth in this decree.



Article 6.

- This decree shall come into force after 180 days following its publication in the Official Journal and shall apply to clinical trials whose application for the sole opinion of the Ethics Committee will be submitted after decree has come into force.



Standard form of insurance certificate

The insurance certificate to be attached to the documents of the interventional clinical trial shall at least contain the information referred to in the following scheme:

- 1. Information concerning the policy
 - 1.1 Insurance company
 - 1.2 Policy number
 - 1.3 Initial Date
 - 1.4 Expiry Date
 - 1.5 Insured (Policy Holder)
 - 1.6 Description of activity (purpose of the policy)



Standard form of insurance certificate

- 2. Covers applying to the protocol submitted to the competent authority and/or the Ethics Committee
 - 2.1 Title of insured protocol:
 - 2.2 No. of trial centres
 - 2.3 Protocol number (if available)
 - 2.4 Number of participants (planned number of patients who will take part in the clinical trial in Italy)
 - 2.5 Tail coverage as discovery period (in months):
 - 2.6 Insureds (list all categories of insured participants)



2.7 Limits of indemnity¹ (this cover shall apply up to the following amounts)

Limit of Liability per Protocol Euro _____

Limit of Liability per Person Euro _____

If the amount of individual indemnities exceeds the above limits of liability for each period of insurance, insurance indemnities recognized to participants shall be reduced pro-rata.

Claims for reimbursement exceeding the above limit of liability shall be borne by the Policy Holder

(sponsor).

¹. The limit of indemnity may vary according to the number of participants or to the risks (see article 2): a limit of at least Euro 1 million in case of damages to every participant shall be provided.





2.8 Deductible

Not provided [] Not enforceable against third parties who claim damages []

2.9 Exclusions (if provided for that specific protocol, please list all exclusions)

Stamp and signature of insurance company