

Annex VA

Insurance certificate Model

Version 27th March 2023

Mr/Ms <<NAME OF REPRESENTATIVE>>, on behalf of the Insurance Company <<NAME OF COMPANY>>, with Tax ID Number <<Tax ID Number>>, and business address at <<ADDRESS OF COMPANY>>, by means of the present document.

HEREBY CERTIFIES:

1. <<NAME OF SPONSOR>> has contracted the aforementioned Company a Civil Liability Insurance Policy <<POLICY number>>, in effect and up to date in payments, in order to cover the damages that could be suffered by a subject as a result of his / her participation in the following clinical trial:

Protocol Code: <<Protocol code>>

Title: <<Title of the clinical trial>>

EudraCT / EUCT Number: <<EudraCT Number / EUCT Number>>

And which is to be conducted in the following sites and foundations:

Site: <<Name of Site>>

Address of Site: <<Postal address of Site>>

Foundation: <<Name of Foundation>>

Address of Foundation (if other): <<Postal address of Foundation>>

Principal investigator: <<Name of Principal Investigator>>

2. This policy also covers the liabilities which could be incurred by the sponsor, principal investigator and his/her research team, including hired clinical researchers, and the hospital or site where the clinical trial is conducted, pursuant to Art. 61 of Royal Decree Law 1/2015, of 24 July, approving the consolidated text of the Act on guarantees and rational use of medicines and medical devices, and in the terms and risks defined in Art. 9 and Art. 10 of Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, Medicinal Product Research Ethics Committees and the Spanish Clinical Studies Registry.



3. The guarantee limits established are: minimum of 250,000 € per person undergoing the clinical trial, with a maximum limit of 2,500,000 € per clinical trial and per year (Art. 10.3 of Royal Decree 1090/2015).

4. The validity period of the insurance shall be from the day <<DD/MM/YYYY OF START OF COVERAGE>> to the day <<DD/MM/YYYY OF END OF COVERAGE>>, renewable for periods of one year until the end of the clinical trial treatment. **This policy does not include limitations different from those defined in Royal Decree 1090/2015.**

5. The aforementioned policy has no deductibles.

6. The aforementioned policy has the following exclusions:

<<STATE EXCLUSIONS INCLUDED IN POLICY>>

Witnesseth and for all relevant purposes, the present agreement is issued in <<City>> on <<Day>> of <<Month>> of <<Year>>

Signed: <<NAME>>