

## Annex V

### Insurance certificate Model

Version 9<sup>th</sup> May 2016

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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: <<EudraCT 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. In addition, it is expressly stated that coverage of the trial is guaranteed for one year after the end of the trial (Art. 10.1 of 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>>