



CLINICAL TRIALS AGREEMENT MODEL INVOLVING MEDICINAL PRODUCTS

AGREEMENT BETWEEN [name of the Sponsor body] and [name of Trial Site] FOR THE CONDUCT OF CLINICAL TRIALS [title of the Trial – sponsor’s code – EudraCT code]

This Agreement is between

[Name of the Sponsor’s legal representative] on behalf of [name of Sponsor - company/organisation/private individual - of the Clinical Trial] (hereinafter known as the “Sponsor”), whose registered office address is [full address], TIN no. [taxpayer identification number].

AND

[Name of Trial Site’s legal representative], on behalf of [name where clinical trial will be conducted] (hereinafter known as the “Trial Site”), whose registered office address is [full address], TIN no. [taxpayer identification number].

It is agreed that the Trial Site and the Sponsor shall participate in the aforementioned clinical trial in accordance with this Agreement.

WHEREAS the Sponsor is interested in conducting the clinical trial [full title of the clinical trial], code [sponsor’s Protocol code number], EudraCT no. [EudraCT number] and internal CREC code [Clinical Research Ethics Committee Protocol code] (hereinafter known as the “Trial”), in the Trial Site and under the direction of Dr. [name of Site Principal Investigator] of the Service [name of the Service of the Site Principal Investigator]. The Protocol of the aforementioned trial is enclosed in Appendix 1 of this Agreement.

WHEREAS the Trial Site, body having legal personality, aims to provide health services and the Service [name of the service where the trial will be conducted] is included in its units.

OBLIGATIONS OF THE PARTIES

- 1 The Trial Site shall ensure that Dr. [name of the Site Principal Investigator], as the Site Principal Investigator, conducts the aforementioned trial, in accordance with conditions specified in the Protocol, having obtained the mandatory favourable

opinion of the Clinical Research Ethics Committee (CREC) and the authorisation of the Spanish Agency for Medicines and Health Products (AEMPS).

The duration of the trial is estimated at [number of months] months from the date of Agreement or until all subjects included have completed their participation in the trial in accordance with the trial Protocol. The duration of the trial may result in early termination if any event described in Article 12 occurs.

- 2 The Trial Site shall ensure that the Investigator observes current legislation, complies with ethical regulations regulating clinical trials with medicinal products, and collaborates in the performance of monitoring visits by the trial monitor, audits by auditors appointed by the Sponsor and inspections by competent health authorities.

- 3 The Sponsor shall not begin at the Trial Site any activity related to the recruitment of subjects for the trial until it has a favourable opinion from the CREC and an authorisation from the AEMPS.

- 4 The Parties shall collaborate and inform each other in relation to the trial.

- 5 The Sponsor has arranged, with accordance to Article 8 of the Royal Decree 223/2004, 6th February, a third-party insurance or financial guarantee covering adequately all damages derived from the participation of subjects in the trial of this Agreement, and shall be up to date in his payment of the premiums for the aforementioned policy. The details of the policy are provided below:

Insurance company:

Policy No.:

- 6 The Sponsor shall include in the Trial Site a minimum of [number of subjects to be included in the Trial Site] subjects¹.
- 7 Estimated direct and indirect costs for conducting this Trial in the Site amount to a total of [estimated amount] euros. This amount corresponds to [amount per assessable subjects] euros per assessable subject, in accordance with the financial statement attached as Appendix 3, which gathers all the economic aspects of the trial according to Royal Decree 223/2004.

The total amount must be paid tot the Trial Site according to the following in-part payments:

- percentage (%) at the beginning of the recruitment of subjects at the Site;
- percentage (%) once half of the data collection registers have been completed or half of the period planned to follow-up subjects included in the Trial Site has elapsed;
- percentage (%) once either all data collection registers have been completed or the follow-up of subjects included in the Trial has ended.

All payments shall be made on presentation of a VAT invoice, applying percentage base rate prevailing on the date the invoice is issued, account no. [account number specified by the Trial Site].

The Sponsor shall make payment within thirty (30) days of the date of receipt of the invoice.

¹It should be noted that, if a clinical trial with competitive recruitment is concerned, the number of subjects to be included may be altered according to the global pace of inclusion. In this case this clause would be replaced by the following:

“The trial defined in this Agreement shall be conducted in this Trial Site on a total of [number of subjects to be included in this Trial Site] subjects. The recruitment of the trial is competitive and this may affect and alter the number of subjects engaged under contract.

Having paid the amount specified above all financial obligations on behalf of the Sponsor under this Agreement are met. In any event, payments shall be made according to the activity performed.

- 8 The Sponsor notes that, in relation to the conduct of this trial in the Site, there have not been and shall not be established any agreements other than this with the Site Principal Investigator or Site collaborating investigators, from which derive further financial compensations or other type of considerations. This clause excludes meeting costs for the organization of the trial, in the case a multicentre trial is concerned, and those facilities the Sponsor may have for the publicity of results obtained from the trial in meetings and scientific publications.
- 9 The Trial Site, the Principal Investigator and his collaborators, the Sponsor and the monitors and/or auditors appointed by the Sponsor guarantee that personal data of subjects included in the trial shall be treated in accordance with Law 15/1999, of Personal Data Protection, and regulations issued under the Law; identity of the subjects included in the trial shall not be disclosed and shall be protected; no personal data of the subjects of the trial shall be transferred save in those circumstances authorised by law.

The Trial Site shall ensure the Investigator preserves confidentiality and secrecy of documents, information, results and data related to the trial procure the restricted circulation of this information, and be responsible for this obligation to be met for all those people that have access to confidential information in accordance with this Agreement.

Monitors and/or auditors appointed by the Sponsor shall have access to clinical information and documentation about subjects included in the Trial that is conducted at the Site, so as to verify the accuracy and reliability of data offered by the Principal Investigator, but they shall not collect personal identification data of the subjects in the trial. The Trial Site shall also provide access to the said data to the inspectors from competent health authorities.

- 10 Results of the trial, all works and reports carried out and all industrial property rights derived from this trial are the exclusive property of the Sponsor.

- 11 The Sponsor shall disclose, once the trial has concluded, the results obtained, either positive or negative, in the public mass media.

Publication of results in scientific books or journals by the Site Principal Investigator shall be made by mutual consent of the Parties; the Sponsor shall be provided with a copy of the manuscript or original so that he can get to know the content and make the appropriate verifications. The Sponsor shall communicate within thirty (30) days to the Principal Investigator whether he agrees or not with the content. If this time expires without any response by the Sponsor, agreement shall be deemed to be accepted and results shall be published by the Investigator. The Sponsor shall expressly request the corresponding authorisations to the Site and to the Site Principal Investigator so as to use their names in scientific publications or in any other mass media for commercial or publicity purposes.

- 12 Trial conducted in the Trial Site may be terminated by any of the Parties or by mutual consent in the following circumstances:

- a) When the trial is interrupted due to any of the circumstances falling within Article 26 of the Royal Decree 223/2004, 6th February.
- b) Failure to include a minimum number of subjects that enable the final assessment of the trial within a reasonable time in accordance with the trial characteristics.
- c) If, from average data analysis of the data or other available information, it is inferred that it is not safe or not justified to continue to administer medication under investigation to the subjects of the trial.
- d) In the event of breach by any of the Parties of any of their obligations under this Agreement.
- e) By mutual written consent.

- f) At the request of any of the Parties with no less than one month prior written notice.

In the event of early termination of the trial, the Sponsor shall pay to the Trial Site the amount for work completed, in accordance with the financial statement attached as Appendix 3 of this Agreement.

The termination of the Trial entails adequate discussion and coordination between the Parties so as to ensure the safety of the subject, decide whether to continue treatment, and the compliance with the existing legal regulations on the issue.

- 13 In the event of a dispute concerning the application or interpretation of this Agreement, the Parties, expressly waiving the jurisdiction that may correspond to the same, submit themselves to the jurisdiction of the Courts and Tribunals of the Trial Site residence.

In witness whereof, the Parties have signed this document in three identical counterparts for one sole purpose.

[Place where the Agreement is signed], [date of signature of the Agreement]

[Signed]

[By the Sponsor]

[By the Trial Site]

[Signature of the Sponsor's legal representative at the Trial Site] [Signature of the Trial Site legal representative]



In witness whereof, the Site Principal Investigator of the trial has signed this Agreement in compliance with his obligations.

[Signature of the Site Principal Investigator of the trial]

Appendix 1. Copy of the trial Protocol of this Agreement

Appendix 2. Commitment of the Site Principal Investigator of the Trial

Appendix 3. Financial statement of the Agreement between [name of the Sponsor body] and [name of the Site where the trial will be conducted] for the conduct of the trial [title of the trial – sponsor's code – CREC code – EudraCT code]

The financial statement must be prepared in accordance with the models and procedures established in each Trial Site to assess the costs in relation to the Trial.

In accordance with Article 30.3 of the Royal Decree 223/2004, 6th February, the financial statement shall include, at least, the following information:

- a) Indirect costs per subject included applied by the Trial Site.
- b) Exceptional indirect costs per subject included: other expenses that would have not produced if the subject had not participated in the Trial, such as additional analysis and examinations, changes in duration and frequency for subjects' care, acquisition of equipments...
- c) Compensation for the subjects included in the Trial.
- d) Compensation for the investigator per subject included.
- e) Payment terms and conditions.