**CONTRACT FOR CLINICAL TRIALS**

**HOSPITAL UNIVERSITARI GERMANS TRIAS i PUJOL**

In Badalona, on\_\_ \_\_\_\_\_\_\_ 20\_\_

**THOSE ASSEMBLED**

On the one hand, Dr Jordi Ara del Rey, with National ID Card No. 40983039-Y, the Territorial Manager of Metropolitana Nord on behalf of the Site **Hospital Universitari Germans Trias i Pujol**, with head office at Crta. de Canyet, s/n, 08916, Badalona, and Tax ID No. Q-5855029-D (hereinafter, the **Hospital**),

On the other handHaga clic aquí para escribir texto., legal representative of **Haga clic aquí para escribir texto.** the laboratory promoting (hereinafter referred as the **Sponsor**) the clinical trial which is the subject of this contract, with offices at Haga clic aquí para escribir texto. and National Id number Haga clic aquí para escribir texto..

On the other hand, Mr. /Mrs. **Haga clic aquí para escribir texto.,** physician, member of the Haga clic aquí para escribir texto. Department, with National Id number Haga clic aquí para escribir texto., acting as principal investigator (hereinafter referred as the “**Principal Investigator**”)

And on the other hand, Mr. Marc Vilar Capella, National ID Card No. 39723267-J, Territorial Economic Manager of Hospital Universitari Germans Trias i Pujol, on behalf of **Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol,** with Tax ID No. G-60805462 (hereinafter, the **Foundation**), domiciled at Ctra. de Canyet, s/n 08916 Badalona, with address for notification purposes: Carretera de Can Ruti, Camí de les Escoles s / n, Edificio Mar, CP 08916 Badalona, ​​Barcelona, and registered in the Register of Foundations of the Generalitat de Catalunya with the number 909, according to powers granted before the notary of Barcelona D. Francisco Armas Omedes, dated July 29, 2016, written with No. 2233 of its protocol

Agree this contract (hereinafter referred as the “**Contract”**) that will be governed by the following articles:

**AGREEMENTS**

**Article 1: Purpose of the Contract**

The purpose of this Contract is the conducting at the Hospital of the Clinical Trial (hereinafter referred as the "**Clinical Trial**"):

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| --- | --- | --- | --- |
| **SPONSOR CODE** |  | **EudraCT** |  |
| **TITLE** |  | | |
| **SPONSOR** |  | | |

The 1st page of the protocol is appended as Annex I to the Contract, which includes the title and version. The complete protocol has been sent to the Center.

The Sponsor agrees not to initiate this trial without having obtained a favorable report from the Ethics Committee for Research with medicinal products (CEIm), the authorization of the Spanish Agency of Medicines and Medical Devices (AEMPS) and the Hospital Universitari Germans Trias i Pujol. Once the authorisations are received they will be sent to the Centre to be attached to the Contract (Annex II: favorable report from the CEIm and Annex III: authorisation from the AEMPS).

The period planned for the conducting of the Clinical Trial at the Centre is **Haga clic aquí para escribir texto.** months.

The Sponsor gives an undertaking that the clinical trial, which is the subject of this Contract, will be complete in accordance with the protocol (hereinafter referred as the "Protocol") which is attached as *Annex I*. In the event that there are substantial modifications to this Protocol, the Sponsor undertakes to communicate them and, if necessary to submit them for prior approval, to the Research Ethics Committee (CEIm).

**Article 2: Principal Investigator and investigation team**

The Clinical Trial, which is the subject of this Contract, will be conducted at Hospital Universitari Germans Trias I Pujol by Dr. Haga clic aquí para escribir texto. of this Centre, who will act as Principal Investigator. The following people will act as his collaborators:



In the event that the Principal Investigator in the Clinical Trial ceases to be a doctor at the Hospital Universitari Germans Trias i Pujol of the Institut Català de la Salut (Catalan Institute of Health), or for whatever reason, ceases to participate in the Clinical Trial, the Principal Investigator undertakes to propose a suitable substitute and to organize his/her acceptance by the Hospital and by the Research Ethics Committee (CEIm) to ensure continuity of the Clinical Trial.

**Article 3: Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol (Germans Trias i Pujol Institut Foundation for Health Sciences Research)**

The Foundation, private foundation for research, will participate as associate manager of this Clinical Trial, its functions being limited to the management of the funds in accordance with the budget attached in *Annex V* and all such actions as may be required to ensure optimum smoothness between the Hospital and the Sponsor, for the best and most efficient realization of the Clinical Trial which is the subject of this Contract.

**Article 4: Monitoring of the trial**

The monitor (hereinafter referred as the "Monitor") of this Clinical Trial will be Mr./Mrs. Haga clic aquí para escribir texto. from Haga clic aquí para escribir texto..

The Sponsor undertakes to transfer to the monitor the obligations set out in this Clause, as well as to make him sign the Confidentiality Agreement attached to this Contract as Annex IV.

The Monitor will have access to the clinical records and other clinical documentation on the subjects included in the Clinical Trial by means of the statement attached as *Annex IV*. Mr. /Mrs. Haga clic aquí para escribir texto. guarantees that he/she will maintain the confidentiality of the data to which he /she might have access during the course of the monitoring and that these will only be used for the purposes of monitoring.

The Monitor will notify, in writing and with sufficient notice, the Hospital, which will inform its clinical departments participating in the Clinical Trial of any monitoring visit, which he/she is to carry out. If during a monitoring visit problems are detected which affect the correct running of the trial, the Hospital will be notify.

Sponsor shall provide the Principal Investigator with information about the running of the trial, if it is a multicentric trial or, in the moment, they are available and also about the serious unexpected adverse events detected by the sponsor with the study drugs.

The Monitor shall provide the information on the Clinical Trial progression monthly, or based on the rate of billing.

If, at the time of signing this Contract, the monitor of the study has not been appointed, the Sponsor will send the Annex IV to the center when they knows their identity to be added to the file of this Contract.

**Article 5: Ownership of results**

Property rights of industrial nature that may arise from the experimental evaluation under this Contract shall belong to the sponsor, without prejudice to the rights that the law grants the investigator/s.

**Article 6: Publications**

1) The results of the trial may not be published until the end of the same, or earlier if it is agreed by the Sponsor, the Center and the Principal Investigator.

2) The sponsor shall not mention the name of the investigators without their permission, unless it is done in reference to already published works.

3) The sponsor allows the publication of the data resulted from the Clinical Trial to journals of recognized scientific prestige and outreach seminars and conferences in the medical professional field provided that in paragraph 1) of this clause is respected.

4) Any publication and/or disclosure of any results in the performed investigations must be agreed by the Sponsor, the Center and the Principal Investigator prior to publication and/or dissemination. In any case, the legitimate interest of the principal investigator will be protected, such as the coordination in the submission of documents to the health authorities or other studies undertaken in the same field, protection of confidential data and information.

5) The previous section 4) must understand the application also to the information obtained in unfinished or suspended before completion Clinical Trial.

6) The investigational staff may not disclose the results of their research to third parties except for the procedures foreseen this Clause.

**Article 7: Confidentiality**

a. Any information, in any form or support, regardless of its nature, that the Parties communicate to each other, whether before, during or after the execution of this Contract, shall be considered as "Confidential Information", including in this category any information generated from the Confidential Information.

The Parties agree to:

1. To treat the Confidential Information as strictly confidential.

2. To use or communicate the Confidential Information exclusively for the execution of the Contract.

3. To use procedures to control the use or transmission of Confidential Information. Likewise, the Parties shall not make copies of the Confidential Information without the prior written consent of the other Party, except for those copies that are required for the execution of the Contract.

4. To restrict access to the Confidential Information to those employees of the Parties who need to know it for the execution of the Contract and to ensure that such employees are aware of the obligations applicable to them by virtue of the provisions hereof.

5. Not to provide Confidential Information to any third party without the prior written consent of the other Party, nor to use it for its own benefit, and to ensure that, in such case, such third party signs a confidentiality commitment in terms equivalent to those of the present clause.

b. The Confidential Information provided by one Party to the other shall at all times be the exclusive property of the former. In the event that such Confidential Information is improved, revised or modified in any way, it shall continue to be the exclusive property of the Party that provided it.

c. At the request of one of the Parties, the other Party shall proceed to destroy or return any Confidential Information in its possession. The destruction or return of the Confidential Information shall not relieve the receiving Party of its obligation to treat such Confidential Information as strictly confidential.

d. The foregoing obligations shall not apply when:

1. After having been provided as Confidential Information, such Confidential Information becomes publicly accessible, without any breach of this Contract has occurred in such circumstance; or

2. It was already legally in possession of the receiving Party, at the time it was provided by the providing Party, or had been obtained independently by the receiving Party prior to and without any use of the Confidential Information received; or

3. The Confidential Information has been lawfully communicated to the receiving Party by a third party who had not acquired it, either directly or indirectly, from the providing Party or who, in such a case, was expressly authorized to disclose it; or

4. It is required to be provided by law or by a judicial or administrative decision. In such case, the Party issuing the Confidential Information shall be informed thereof, and only the Confidential Information strictly required shall be disclosed.

e. The Parties undertake to adopt the necessary measures for the maintenance of secrecy and confidentiality among the personnel under their responsibility, being responsible for the breach of this obligation, whether by their employees, associates, subcontractors, or any other person to whom they have disclosed the Confidential Information.

f. The confidentiality obligations arising from this article shall be of indefinite duration and shall continue even after the contractual relationship between the Parties has terminated.

**Article 8: Protection of personal data**

In accordance with the provisions of Article 3 of R.D. 1090/2015, the Parties undertake to process the personal data of the subjects participating in the Trial in accordance with the national and European regulations in force on the matter and, specifically, in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) (hereinafter, the "Regulation (EU) 2016/679") and the Organic Law 3/2018 of 5 December on the Protection of Personal Data and guarantee of digital rights.

Likewise, the Parties undertake and are responsible for enforcing such regulations and their duty of confidentiality to their employees and to those third parties that subcontract and participate in any way in the processing of information of the subjects participating in the Trial.

Any processing of the participants' data for the purposes of the Trial is prohibited without the pertinent legitimacy.

The HOSPITAL and the SPONSOR are, respectively, controller for the processing of the personal data of the participating subjects in accordance with the provisions of Regulation (EU) 2016/679. The SPONSOR will only have access to information relating to subjects participating in this Trial after pseudonymization, unless informed consent, a regulation having the force of law, or a judicial authority so permits.

Monitors and/or auditors appointed by the SPONSOR will have access to clinical information and documentation relating to Trial participants for the purpose of verifying the accuracy and reliability of the data provided by the Principal Investigator. The HOSPITAL will also provide access to these data to inspectors of the competent health authorities, when required by the regulations in force.

The processing of personal data of the subjects participating in the Trial by monitors, auditors and other third parties designated by the SPONSOR may only be carried out after verification of compliance with the guarantees and corresponding legitimacy in accordance with Regulation (EU) 2016/679.

For the purposes of the provisions of Regulation (EU) 2016/679 and the corresponding implementing regulations, the Parties hereby state that the personal data contained in this Contract or in the previous preparatory documents of the same, shall be for the exclusive use for the purposes of the reciprocal relations between the Parties, shall not be transferred and shall be kept for the duration of this Contract. The Parties undertake to provide the owners of the data provided with this information, as well as to inform them that they may write, identifying their identity, to the respective addresses indicated in the heading of this Contract to exercise their rights of access, rectification, suppression, opposition, limitation, and portability.

**Article 9: Budget for the trial**

The budget for the Clinical Trial, which is the subject of this Contract, is detailed in *Annex V*.

**Article 10: Form of payment and terms**

The SPONSOR agrees on the payment to the FOUNDATION **Haga clic aquí para escribir texto.** € for each evaluable patient. The number of estimated patients to be included is **Haga clic aquí para escribir texto.**, which means a maximum amount of **Haga clic aquí para escribir texto.** € . The amount of the budget for the Clinical Trial will be effect with the following terms:

Provided another form of payment is not specifyied in this Contract, all the payments of the Trial will be made on a quarterly basis.

After the end of each quarter, the Sponsor will pay the total of the budgeted costs that have taken place during that quarter, except for the last payment, which will be made when all the activities related to the Trial are concluded.

The first quarter shall begin on the date of inclusion of the first patient.

In addition, the Sponsor agrees to pay the Foundation the amount of 1,500.00 Euros (+ VAT, if applicable), for administrative management of the Contract once the signature process ends. The payment of this amount will not be conditioned to the effective performance of the Clinical Trial or to the approval of the Trial by the CEIm or the AEMPS.

Regarding the opening of Pharmacy Service: a one-off non-refundable payment of 1,500 euros (+ VAT, if applicable) will be made once the contract is signed, for their intervention in the reception, storage, dispensing and control related to the management of the study medication.

The FOUNDATION will send an invoice for the amounts paid to it by the SPONSOR for each payment as it becomes due.

Bank data of the FUNDATION for payments:

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| *Account holder name:* | Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol  Ctra. de Canyet, s/n, 08916, Badalona, Spain  CIF: G-60805462 / VAT Number: ES G60805462 |
| *Bank Name* | BBVA (Banco Bilbao Vizcaya Argentaria, S.A.) |
| *Bank Address* | Plaça Catalunya, 5 Pl. 1ª, 08002, Barcelona |
| *Account Number* | 0182 6035 46 0201600421 |
| *IBAN Code* | ES16 0182 6035 46 0201600421 |
| *SWIFT Code* | BBVAESMMXXX |

Fiscal data of the SPONSOR for invoicing:

|  |  |
| --- | --- |
| *Fiscal Name* |  |
| *NIF / CIF / VAT Number* |  |
| *Address* |  |
| *Contact Person* |  |
| *Phone* |  |
| *E-Mail* |  |
| *Invoice delivery address*  *(different from previous)* |  |

In the event that, for any reason unrelated to the HOSPITAL where the trial is being conducted and beyond the control of the Principal Investigator, the conducting of the Clinical Trial is suspended after it has started, the SPONSOR will pay, in a single payment, all the expenses which have been incurred by the Clinical Trial up to the date of suspension and according to the number of patients included and the visits and physical examination carried out.

In the event that the Clinical Trial is suspended for a reason attributable to the Principal Investigator or due to a decision by the HOSPITAL, without contributing to the causes behind this suspension, the FOUNDATION will return to the Sponsor the amount which remains from the difference between the expenses generated by the Clinical Trial up to the date of suspension (in accordance with the budget and the number of patients included and visits and physical examinations carried out) and the total amount of money paid by the SPONSOR in the various periods in which payments have been made.

Financial transfers from the funds of the FOUNDATION to the Institut Català de la Salut (Catalan Institute of Health) will be carry out in accordance with the provisions of the clause of the agreement concluded between both bodies.

**Article 11: Insurance for the clinical trial**

The Sponsor declares that it has taken out a civil liability insurance policy with the company Haga clic aquí para escribir texto., which covers any damage that might occur as a result of clinical trial which is the subject of this Contract on the participating subjects and the head of the Centre in accordance with the provisions of Article 9 of Royal Decree 1090/2015.

**Article 12: Compliance by the contracting parties with current legislation**

The parties undertake to comply with the duties and obligations imposed by all such legal standards as apply to the running of clinical trials and specifically with Law 1/2015, dated 24th of July, that modified the Law on Guarantees and Rational Use of Medicines and Medical Devices (Law 29/2006, of 26th of July) and with Royal Decree 1090/2015 which establish the requirements for the conducting of clinical trials of medicines and the regulations which confirm them.

In the same way, the parties agree to maintain the ethical standards recognized in the Helsinki Declaration and subsequent versions.

Concerning the provision of the medication the sponsor shall implement its legal obligations in accordance with RD 1090/2015 (Article 39.3-f).

In regard of the medication supply, the clinical trial sponsor will abide by their obligations, as established in the Royal Decree 1090/2015, article 39.3 subsection f. Keeping administering an investigational medicinal product to the subjects that have finished taking part in a clinical trial without a market authorisation in Spain shall be subject to the obligations laid down in article 31 of the Royal Decree 1090/2015.

**Article 13: Governing Law and Jurisdiction**

For the resolution of any dispute, which might arise in relation to the fulfilment, and performance of this Contract, the parties shall submit to arbitration by the Director of the Catalan Health Service or, alternatively, the referee appointed by the Arbitral Tribunal of Barcelona.

In the jurisdiction scope, the parties are subject to the courts of the city of Barcelona.

And as evidence of their agreement with its contents, the parties sign this Contract by digital signature, coming into effect on the date of the last signature.

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| ***Dr. Jordi Ara del Rey***  *Hospital Universitari Germans Trias i Pujol* |  | ***Mr. /Mrs. Haga clic aquí para escribir texto.***  *Legal Representative of Sponsor* |
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|  |  |  |
| ***Mr. Marc Vilar Capella***  *Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol* |  | ***Dr. /Dra. Haga clic aquí para escribir texto.***  *Principal Investigator*  *Hospital Universitari Germans Trias i Pujol* |

**ANNEX I**

**1st PROTOCOL PAGE**

**ANNEX II**

**FAVOURABLE REPORT OF THE CEIM**

**ANNEX III**

**AUTHORIZATION OF THE AEMPS**

**ANNEX IV**

**MONITOR CONFIDENTIALITY AGREEMENT**

1. The relationship contained in this document integrates professionals outside the Hospital Universitari Germans Trias i Pujol who can access personal data related to the protocol code Haga clic aquí para escribir texto., entitled "Haga clic aquí para escribir texto."
2. Knowing the rules that regulate the confidentiality of personal data.

**MANIFEST:**

1. They know and understand that all the personal data of the subjects of the trial and of how many others are known by reason of the same are reserved and confidential.
2. They undertake to keep under strict confidentiality and reservation the personal data they know about their participation in the trial, refraining from divulging or using them, in any way, regardless of the objective of the trial that legitimizes access to them.

List of professionals and contact information:

* Name: Haga clic aquí para escribir texto.
* Company: Haga clic aquí para escribir texto.
* Phone: Haga clic aquí para escribir texto.
* E-mail: Haga clic aquí para escribir texto.
* ID Number: Haga clic aquí para escribir texto.

*Signed:*

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| ***Mr. /Ms. Haga clic aquí para escribir texto.***  *Study’s Monitor* |

**ANNEX V**

**BUDGET FOR THE CLINICAL TRIAL**