**OBSERVATIONAL STUDY CONTRACT WITH MEDICINAL PRODUCT**

**HOSPITAL UNIVERSITARI GERMANS TRIAS i PUJOL**

In Badalona, on \_\_ of \_\_

**THOSE ASSEMBLED**

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

On the other hand, Mr. / Ms. / Mr. Click here to enter text.on behalf of and as **Click here to enter text.,** the laboratory pomoting the Observational Study with Medicinal Products (hereinafter, the “**SPONSOR”**) subject of the present contract and with registered office at Click here to enter text. and with Tax Identification Number Click here to write text.

On the other hand, Mr/Mrs. **Click here to enter text.** by profession Click here to enter text. member of the Department of Click here to enter text. of the Hospital Universitari Germans Trias i Pujol and with Tax Identification Number Click here to write text.as principal Principal Investigator (hereinafter, the “**PRINCIPAL INVESTIGATOR**).

And on the other hand, Mr. Marc Vilar Capella, with National ID Card No. 39723267-J, Territorial Economic Director of the Hospital Universitari Germans Trias i Pujol, on behalf of the **Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol**, with Tax Identification Number G-60805462 (hereinafter, the “**Foundation”**) and 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 under number 909, according to powers granted before the notary of Barcelona D. Francisco Armas Omedes, dated 29 July 2016, written No. 2233 of its protocol.

The Hospital, the SPONSOR, the Foundation and the PRINCIPAL INVESTIGATOR may be referred to jointly as the "Parties" and individually as the "Party".

They enter into this observational study contract with medicinal product(hereinafter referred to as the **"Contract"**) which shall be governed by the following clauses:

**AGREEMENTS**

**Article 1: Purpose of the contract**

The purpose of this Contract is to carry out at the Hospital Universitari Germans Trias i Pujol the Observational Study with Medicinal Products indicated below (hereinafter "**Study**"):

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

The first page of the protocol is appended as *Annex I* to this Contract, which includes the title and version. The complete protocol has been sent to the Hospital.

The SPONSOR undertakes not to initiate the present study without having obtained a favourable report from the Ethics Committee for Research with Medicinal Products (CEIM) (attached as Annex II).

The expected timeframe for the completion of this Study at the HOSPITAL is of **Click here to write text.** months.

The SPONSOR undertakes to ensure that the Study that is the subject of this Contract will be complete in accordance with the protocol (hereinafter "**Protocol**") which is attached as *Annex I*. In the event that there are modifications to this Protocol, the SPONSOR undertakes to communicate them and, if necessary, to submit them to the Ethics Committee for Clinical Investigation for prior approval.

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

The Study, which is object of this Contract, will be conducted in this HOSPITAL by Dr. /Dr. Click here to write text. of the Hospital Universitari Germans Trias i Pujol who will act as principal Principal Investigator. The following people will act as her/his collaborators:



In the event that the PRINCIPAL INVESTIGATOR ceases to be a doctor at the Hospital Universitari Germans Trias i Pujol, of the Institut Català de la Salut, or, for whatever reason, ceases to participate in the Study, the PRINCIPAL INVESTIGATOR undertakes to propose a suitable replacement and to arrange for his/her acceptance by the Hospital Universitari Germans Trias i Pujol and the Ethics Committee for the Clinical Research (CEIC) of the Hospital Universitari Germans Trias i Pujol to ensure the continuity of the Study.

**Article 3: Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol**

The Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol, a private Foundation for research at the Hospital Universitari Germans Trias i Pujol, participates as an associated manager of this Study, limiting its functions to the management of the funds in accordance with the budget attached as *Annex IV* and all such actions as may be required to ensure optimum smoothness between the Hospital Universitari Germans Trias i Pujol and the SPONSOR, for the best and most efficient realization of the Study that is the object of this Contract.

**Article 4: Monitoring of the Study**

In case monitoring visits are to be carried out, the monitor of this Study will be Mr/Mrs/Ms. Click here to enter text. who belongs to the company Click here to enter text..

The monitor of the Study will have access to the medical records and other clinical documentation of the subjects included in the Study. By means of the letter attached as Annex III, Mr/Mrs/Ms. Click here to enter text. guarantees that he/she will maintain the confidentiality of the data to which he/she will have access when carrying out the monitoring and that these will only be used for monitoring purposes.

The monitor will notify, in writing and with sufficient notice, the Hospital Germans Trias i Pujol University Hospital, which will inform its clinical departments participating in the Study, and the Ethics Committee for Clinical Investigation of the Hospital Universitari Germans Trias i Pujol of any monitoring visit carried out.

If during a monitoring visit are detected problems that affect the correct running of the Study, the Hospital Universitari Germans Trias i Pujol will be notified.

The SPONSOR undertakes to provide the PRINCIPAL INVESTIGATOR with information about the running of the Study, if it is multicentric, and of the results obtained at the end of the Study or at the time they become available, and also about the serious unexpected adverse events detected by the SPONSOR with the products under Study.

It also undertakes to provide any new information available on the product during the evolution of the study.

If, at the time of signing this Contract, the monitor of the Study has not been appointed, the SPONSOR undertakes to transfer to the monitor the obligations established in the present Clause*,* when he/she knows the identity of the same, as well as to make him/her sign the Confidentiality Agreement attached to the present Contract as *Annex III* and to send it to the HOSPITAL to be added to the file of the present Contract.

**Article 5: Ownership of results**

Property rights of an 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 granted to the Investigator/s.

**Article 6: Publications**

1) The results of the Study may not be published until the end of the same, or earlier if agreed by the HOSPITAL, the PRINCIPAL INVESTIGATOR(s) and the SPONSOR.

2) The SPONSOR shall not mention the names of Investigators without their authorisation, unless it is done in reference to already published.

3) The SPONSOR allows the publication of the data obtained form the Study to journals of recognised scientific prestige and its dissemination in seminars and conferences within the medical professional field, provided that the provisions of paragraph 1) and 2) of this Clause are respected.

4) Any publication and/or disclouse of any kind of results of medical research carried out with the medicinal product Click here to enter text. shall be agreed by the HOSPITAL and the PROMOTER, prior to publication and/or disclosure. In any case, the legitimate interest of the PRINCIPAL INVESTIGATOR will be protected, such as coordination in the submission of documents to health authorities or other studies undertaken in the same field, protection of confidential data and information.

5) The previous section 4) shall also apply to information obtained in studies not completed or suspended before their completion.

6) The investigational staff may not disclose the results of its research to third parties, except for the procedures forseen in this Clause.

**Article 7: Confidentiality**

1. Any information, in any form or medium, whatever its nature, transmitted by the Parties, whether before, during or after the signature of this Contract, shall be conHospitalred as "Confidential Information", including information generated from the Confidential Information.

The parties undertake to:

1. Treat Confidential Information as strictly confidential.
2. Use or transmit the Confidential Information exclusively for the performance of the Contract.
3. Use procedures to control the use or transmission of Confidential Information. Furthermore, the Parties shall not make copies of Confidential Information without the prior written consent of the other party, except for copies required for the performance of the Contract.
4. Restrict access to Confidential Information to those employees of the Parties who need to know it for the performance of the Contract and ensure that such employees are aware of their obligations hereunder.
5. Not to provide Confidential Information to any third party without the prior written consent of the other Party, or to use it for its own benefit, and to ensure that, in such case, such third party signs a confidentiality undertaking on terms equivalent to those of this clause.
6. Confidential Information provided by one Party to the other Party shall at all times remain the exclusive property of the first Party. In the event that such Confidential Information is enhanced, revised or modified in any way, it shall remain the exclusive property of the Party that provided it.
7. At the request of a Party, the other Party shall destroy or return any Confidential Information in its possession. The destruction or return of Confidential Information shall not relieve the receiving Party of its obligation to treat such Confidential Information as strictly confidential.
8. The above obligations shall not apply where:

1. After having been provided as Confidential Information, it becomes publicly available, without any breach of this Contract having occurred; or

2. It was already lawfully in the 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 Confidential Information received; or

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

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

1. 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.
2. The confidentiality obligations arising from this clause shall be of indefinite duration and shall continue even after the termination of the contractual relationship between the Parties.

**Article 8: Protection of Personal Data**

In accordance with the provisions of article 5 of Royal Decree 957/2020, which regulates observational studies with medicinal products for human use, the Parties undertake to process the personal data of the subjects participating in the Study 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 "Regulation (EU) 2016/679") and Organic Law 3/2018 of 5 December on the Protection of Personal Data and the guarantee of digital rights.

Likewise, the Parties undertake and are responsible for ensuring that their employees and third parties who subcontract and participate in any way in the processing of the information of the subjects participating in the Study comply with these regulations and their duty of confidentiality.

Any processing of participants' data for the purposes of the Study, without the relevant legitimation, is prohibited.

The HOSPITAL and the SPONSOR are, respectively, controllers 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 the subjects participating in this Study after pseudonymisation, unless informed consent, a regulation with the status of law or a judicial authority so permits.

The monitors and/or auditors appointed by the SPONSOR may have access to the clinical information and documentation relating to the participants in the Study, for the purpose of verifying the accuracy and reliability of the data provided by the PRINCIPAL INVESTIGATOR(s). 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 Study by monitors, auditors and other third parties appointed 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 holders 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 Study**

The budget for the Study, which is the subject of this Contract, is as detailed in *Annex IV*.

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

The SPONSOR agrees on the payment to the FOUNDATION the amount of **Click here to enter text.** Euros per complete and evaluable patient. The foreseen number of patients to be included in the study is **Click here to enter text.**which would mean a maximum amount of **Click here to write text.** Euros.

Provided another form of payment is not specified in this Contract, all payments for the study shall be made on a quarterly basis.

After the end of each quarter, the SPONSOR shall pay the total budgeted costs incurred during that quarter, except for the last payment, which shall be made upon completion of all activities related to the Study.

The first quarter shall start from 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 the administrative management of the Contract once the signing process has been completed. The payment of this amount shall not be conditioned to the effective performance of the Study or its approval by the CEIm or the AEMPS.

For the amounts paid by the SPONSOR to the FOUNDATION, the latter will issue an invoice for the amount paid in each of the payments.

The FOUNDATION's bank details to pay the amounts are:

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

The fiscal data of the SPONSOR for invoicing:

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| --- | --- |
| *Fiscal Name* |  |
| *NIF / CIF / VAT Number* |  |
| *Address* |  |
| *Contact Person* |  |
| *Telephone* |  |
| *E-Mail* |  |
| *Billing Address*  *(if different from above)* |  |

In the event that, for any reason unrelated to the centre where the Study is being conducted and beyond the control of the PRINCIPAL INVESTIGATOR, the conducting of the Study is suspended after it has started, the SPONSOR will pay, in a single payment, all the expenses generated by the Study up to the date of suspension and in accordance with the number of patients included, and the visits and physical examinations carried out.

In the event that the Study is suspended for a reason attributable to the PRINCIPAL INVESTIGATOR or by decision of the HOSPITAL, without there being causes for this suspension, the FOUNDATION will return to the SPONSOR the amount which remains from the difference between the expenses generated by the Study 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 amount resulting from the sum of the money paid by the SPONSOR in the various periods in which payments have been made.

Finantial transfers from the funds of the Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol to the Institut Català de la Salut (Catalan Institute of Health), will be carried out in accordance with the clause of the agreement signed between both entities.

**Article 11: Insurance for the Study**

In accordance with Royal Decree 577/2013 and Circular 15/2002 (section 5 of Annex VI), the observational studies are exempt from the requirement for subscription of an insurance.

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

The Parties undertake to comply with the duties and obligations imposed by all such legal regulations applicable to observational studies with medicinal products and, specifically, without limitation but not limited to, the Law 29/2006 of 26th July, on Guarantees and Rational Use of Medicines and Medical Devices (hereinafter, the Medicines Act); Royal Decree 577/2013, of 26th  July, which regulates the Pharmacovigilance of medicinal products for human use (hereinafter, Pharmacovigilance RD); Royal Decree 957/2020, of 3 November, which regulates observational studies with medicinal products for human use (hereinafter, Guidelines), the local legislation applicable in each case, and Organic Law 3/2018, of 5 December, on the Protection of Personal Data and guarantee of digital rights.

In addition, the Parties undertake to abide by the ethical standards set out in the Declaration of Helsinki and subsequent revisions.

**Article 13: Arbitration**

For the resolution of any dispute that may arise in relation to the fulfilment and performance of this Contract, the Parties shall submit to the arbitration of the Director of the Servei Català de la Salut or, alternatively, to the referee appointed by the Arbitration Court of Barcelona.

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

And as evidence of conformity with its contents, the Parties sign the present Contract by means of digital signature, entering into force on the date of the last signature.

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| ***Dr. Jordi Ara del Rey***  *Hospital Universitari Germans Trias i Pujol* |  | ***Mr/Mrs.* Click here to write text.**  *Legal Representative of the Promoter* |
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|  |  |  |
| ***Mr. Marc Vilar Capella***  *Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i Pujol* |  | ***Dr. /Dr.* Click here to write text.**  *Principal Principal Investigator*  *Hospital Universitari Germans Trias i Pujol* |

**ANNEX I**

**1ST PAGE PROTOCOL**

**ANNEX II**

**SUBMISSION TO THE CEIC REPORT**

**ANNEX III**

**MONITOR CONFIDENTIALITY AGREEMENT**

The relationship contained in this document integrates professionals outHospital the Hospital Universitari Germans Trias i Pujol who can access personal data related to the study with protocol code Click here to enter text.entitled "Click here to write text.".

1. Kwowing the rules that regulate the confidentiality of personal data.

**MANIFEST:**

1. They know and acknowledge that all personal data of the subjects of the Study and any other data that may become known by reason of the Study are reserved and confidential.
2. They undertake to maintain strict confidentiality and reserve the personal data that they become aware of as a result of their participation in the Study, refraining from disclosing or using them, under any circumstances, outHospital the purpose of the Study that legitimises access to them.

List of professionals and contact details:

* Name:
* Company:
* Contact telephone number: Click here to write text.
* E-mail:
* ID Number:

*Signed:*

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|  |
| ***Mr/Mrs.***  *Monitor* |

**ANNEX IV**

**BUDGET OF THE STUDY**