**CONTRACT FOR POST-AUTHORIZATION STUDIES**

**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 **SITE**),

On the other hand, Haga clic aquí para escribir texto., legal representative of **Haga clic aquí para escribir texto.** the laboratory promoting (hereinafter referred as the "**SPONSOR**") the STUDY which is the subject of this contract, with domicile 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. 39723267J, 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 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 post-authorization Study (hereinafter referred as the "**STUDY**"):

|  |  |
| --- | --- |
| **SPONSOR CODE** |  |
| **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.

Sponsor agrees not to initiate this study without obtaining a favorable report from the Ethics Committee for Research with Medicinal Products (CEIM) of the Hospital Universitari Germans Trias i Pujol (attached in Annex II).

The study has been notified to the Spanish Agency of Medicines and Medical Devices (AEMPS) (attached as Annex III).

For Post-authorization study with prospective follow-up (EPA-SP), the Sponsor agrees not to initiate this study without the authorization of the competent Autonomous Community (which replaces Annex III).

Once the authorisations are received they will be sent to the centre to be attached to the contract.

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

The Sponsor gives an undertaking that the STUDY that 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 modifications to this protocol, the Sponsor undertakes to communicate them and, if necessary to submit them for prior approval, to the Ethics Committee for Clinical Investigation of the HOSPITAL.

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

The STUDY, which is the subject of this contract, will be conducted at this Centre by Dr. /Dra. Haga clic aquí para escribir texto. of the HOSPITAL who will act as Principal Investigator. The following people will act as his collaborators:

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

**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 at the Hospital Universitari Germans Trias i Pujol, will participate as associate manager of this STUDY, 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 STUDY which is the subject of this contract.

**Article 4: Monitoring of the study**

In the event that sponsor makes monitoring visits, the monitor (hereinafter referred as the "Monitor") of this STUDY will be Mr. /Mrs. Haga clic aquí para escribir texto. from the company Haga clic aquí para escribir texto..

The Monitor will have access to the clinical records and other clinical documentation on the subjects included in the STUDY 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 STUDY and the Ethics Committee for Clinical Research of the HOSPITAL, of any monitoring visit, which he/she is to carry out.

If during a monitoring visit are detected problems that affect the correct running of the STUDY, the HOSPITAL will be notified.

The Sponsor shall provide the Principal Investigator with information about the running of the STUDY, if it is multicentric, and the results obtained at the end of the STUDY 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.

In addition, shall be provided any new information about the product that becomes available during the STUDY.

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 STUDY may not be published until the end of the same, or earlier if it is agreed by both parties.

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 STUDY 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 both parties prior to publication and/or dissemination. In any case, the legitimate interest of the principal investigator will be protect, 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 STUDY.

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 of the information**

The SPONSOR undertakes to respect strictly the confidentiality of everything that may be linked to the subjects of the HOSPITAL included in the STUDY under the contract as well as all hospital’s clinical documentation to which the sponsor has access.

Regardless of the commitments made by the principal investigator, HOSPITAL undertakes to ensure maximum confidentiality of their participation in the STUDY, the content of the STUDY protocol and any information, related to the STUDY under this contract that is provided by the sponsor. Public disclosure of this information will make only with the agreement, expressed in writing, of the sponsor.

The personal data of the subjects included in the STUDY will be treated in accordance with the established provisions of the current legislation: 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); Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights. No personal data of the STUDY subjects, except in circumstances where the law permits shall be transferred.

The Institut Català de la Salut recognizes the property of the sponsor of the data, the results derived from the STUDY under the contract.

**Article 8: Budget for the study**

The budget for the STUDY, which is the subject of this contract, detailed in *Annex V*.

**Article 9: 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.**€.

Provided another form of payment is not specifyied in this contract, all the payments of the Study 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 1,000.00 Euros (+ VAT), 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 Study or to the approval of the Trial by the CEIm or the AEMPS.

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:

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:

|  |  |
| --- | --- |
| *Account holder name:* | Fundació Institut d'Investigació en Ciències de la Salut Germans Trias i PujolCtra. de Canyet, s/n, 08916, Badalona, SpainCIF: 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 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 which have been incurred by the STUDY 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 STUDY 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 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 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 10: Insurance for the study**

In accordance to Royal Decree 577/2013 and Circular 15/2002 (paragraph 5 of Annex VI), the post-authorization observational studies are exempt from the requirement for subscription of insurance.

**Article 11: Compliance by the contracting parties with current legislation**

Both parties undertake to comply with the duties and obligations imposed by all such legal standards as apply to the running post-authorization observational studies and specifically, without limitation but not limited to, the Law 29/2006 dated 26th of July on Guarantees and Rational Use of Medicines and Medical Devices with the Royal Decree 577/2013 dated 26th of July which establish the requirements for the pharmacovigilance of medicinal products for human use and the Order SAS/3470/2009 dated 16th December publishing guidelines for conducting post-authorization observational studies with medicinal products for human use, the local legislation applicable and the Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights.

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

**Article 12: 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 Barcelona.

And as evidence of their agreement with its contents, the parties sign this contract in quadruplicate and for a single purpose, in the place and on the date indicated at the beginning.

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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**

**SUBMISSION TO THE CEIC**

**ANNEX III**

**NOTIFICATION TO 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 study 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 study, refraining from divulging or using them, in any way, regardless of the objective of the study 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.

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

**ANNEX V**

**BUDGET OF THE STUDY**