**CONTRACT FOR CONDUCTING POST-MARKETING STUDIES OF A HEALTH PRODUCT**

Title: *(complete title of study)*

Study Code: *(code of Study assigned by Sponsor)*

In San Sebastian, on \_\_\_\_\_ of \_\_\_\_\_ 201\_,

1. **By and between**

**(Centre)** Mr. José Manuel Ladrón de Guevara, ID number 15241009-Jas the General Manager of Organización Sanitaria Integrada Donostialdea and in representation of said Organisation with address at Pº Dr. Beguiristain s/n, San Sebastián (Gipuzkoa)with Post Code 20014 in San Sebastian and TIN S-5100023J, (hereinafter, the Centre).

**(Sponsor)** And Mr/Ms. *(name of the legal representative of the Sponsor)*, on behalf of and in representation of  *(add name of company )* (hereinafter, “**Sponsor**”), with company address at *(add complete address )* and TIN *(add tax identification number)* with the legal capacity to sign this contract.

 **(Principal Investigator)** And, *(name of Principal Investigator)*, with National Identity Card number *(add ID number)* and with address for the purposes of notifications at the *(add the service he/she belongs to)* Service of the Centre. He/She acts on his/her own behalf and in his/her own representation, as the Principal Investigator, (hereinafter, also called the “**Principal Investigator**”).

*Fill in details below in the event of an organisation that acts in representation of the Sponsor.*

**(C.R.O acting in representation of the Sponsor)** Mr/Ms. *(name of legal representative of the company/organisation) as (add function presented)* of the company *(name of company)* and in representation of said Organisation with address at *(complete address of the company )* and with TIN *(Tax identification number)* hereinafter the “**CRO**”) acting in representation of *(add name of company)* (hereinafter, the “**Sponsor**”), with business address at *(add complete address )* and TIN *(add tax identification number)* in accordance with Annexe III: Powers to sign on behalf of the Sponsor.

All the parties recognise each other's necessary capacity to enter into this contract.

1. **They Manifest and Declare**
2. That the Sponsor is interested in conducting a Clinical Trial with Health Product, the identification details of which are described in the heading, and whose objective and purpose are described in the following terms *(add objective)*, of the Product *(add the product)*.
3. That to this end, the Sponsor has selected the most suitable Principal Investigator according to his/her qualifications and resources available to carry out the Study at the centre facilities, in accordance with the contract and the Study Protocol.
4. That the fundamental aims of the Biodonostia Institute are to promote the biomedical and epidemiological investigation of public health and health services, to scientifically explore the programmes and policies of the health service and to preferentially enhance transnational research geared to accelerating the transfer of scientific knowledge to clinical practice, in accordance with international recommendations within the territorial scope of Gipuzkoa, by virtue of the collaboration agreements with Osakidetza/SVS, under which it is entrusted with the management of R&D is being carried out within its organisation.
5. That the Centre is willing to carry out the study under the terms and conditions agreed to by the Sponsor and BIODONOSTIA.

Therefore, and in compliance with the foregoing, the parties enter into this Contract for the carrying out of a Research Study (hereinafter also called the “**Contract**”), based on the following.

1. **Terms and Conditions**
2. **Purpose**
	1. The purpose of this Contract is to develop, on behalf of and in the name of the Sponsor, the Clinical Study, identified as *(complete title of study)* with code *(add code)* (hereinafter, the “**Study**”), that shall be carried out on the premises of the Centre, under the direction and responsibility of the Principal Investigator.
	2. The estimated number of patients to be included shall be *(add estimated number of participants)* patients at this centre.
	3. The Sponsor tasks the Principal Investigator with the recruitment procedures of the patients required for the Study to be adequately conducted. The patients should be selected in accordance with the criteria and deadlines established in the Protocol, without prejudice to the option of the parties extending the initially agreed period.
3. **Terms governing implementation.**
	1. Protocol

The Study shall be conducted subject to the conditions and requirements of the Protocol attached to this Contract as Annexe l (hereinafter the “Protocol”), respecting legislation currently in force and the standards of BCP.

* 1. Commencement and duration of Study.
		1. Commencement of the Study shall be determined by the favourable opinion of the corresponding Ethics Committee for Clinical Research (hereinafter, the CEIC), the agreement of the centre and the signing of this contract by all the parties.
		2. The duration of the Study shall be established in the Protocol *(add number of months)* and shall be calculated as starting from the signing of this Contract or a favourable opinion from the CEIC.
		3. The Sponsor undertakes to issue a written annual report on the progress of the study to BIODONOSTIA and to give notice of the end of same within 3 months after termination.
	2. Modifications**.**
		1. Any important modification of the Protocol should be agreed by Sponsor and the Principal Investigator and should receive the approval of the CEIC. The parties concerned shall assess if it is necessary to make any changes to the Contract and/or annexes of same by means of addenda.
		2. Any change of the persons participating in the Study should be agreed by the parties and should receive approval from the CEIC if applicable.
	3. Legal ethical standards.

The Study shall be conducted subject to the regulations applicable at the time of signing this Contract and for the duration thereof, in particular the following:

* + 1. Law 41/2002, of 14 November, on the autonomy of the patient and rights and obligations with regard to clinical information and documentation.
		2. Decree 3/2005 (Basque Country), of 11 January, creating the Ethics Committee for Clinical Research of the Autonomous Community of the Basque Country.
		3. Law 14/2007, of 3 July, on biomedical research.
		4. Royal Decree 1720/2007, of 21 December, approving the implementing Regulations of Organic Law 15/1999, of 13 December, on Protection of Personal Data.
		5. [Royal Decree 1591/2009, of 16 October](http://www.aemps.gob.es/legislacion/espana/productosSanitarios/docs/Directiva_93-42-CEE/rcl_2009_2105.pdf) regulating health products
		6. [Royal Decree 1616/2009, of 26 October](http://www.aemps.gob.es/legislacion/espana/productosSanitarios/docs/Directiva_90-385-CEE/rcl_2009_2106.pdf%22%20%5Co%20%22PDF%20file%20%28166%20KB%29%20.%20Opened%20in%20a%20new%20window%20/legislacion/espana/productosSanitarios/docs/Directiva_90-385-CEE/rcl_2009_2106.pdf) , regulating active implantable medical products.
		7. It is agreed that the study shall be conducted in accordance with the Ethical Principles contained in the Helsinki Declaration in its most recent version.
	1. Informed consent.

The Study shall be carried out with the maximum respect for patients' rights, informing them clearly and accurately of the objective of the Study and of the possible benefits and risks of participation in same. Before including any patient in the Study, informed consent shall be obtained from same, in accordance with legislation currently in force.

* 1. Access.
		1. The CEIC shall have access at all times to documentation about the Study needed to monitor same as established in the regulatory legislation, especially informed consent of the patients that participate in same, if this is necessary.
		2. The competent Health Authority and the staff appointed by the Sponsor may have access to data for monitoring purposes and to verify the accuracy of the data facilitated by the Principal Investigator about the participants in the Trial and the clinical information and documentation about them that is in the Centre to verify the accuracy and reliability of same.
		3. The Principal Investigator should ensure that the Sponsor's staff respect the standards of confidentiality with regard to any information about the participants of the Study.
		4. The Centre shall facilitate access to said data to the CEIC and the inspectors of the competent health authorities and the Sponsor's staff.
	2. Ownership and Publication of results.
		1. The industrial and intellectual property rights deriving from the data, results, discoveries and patentable or non-patentable inventions that are obtained or developed over the course of the study shall belong exclusively to the Sponsor as sole owner thereof.
		2. The Sponsor is obliged to publish the results of the study, whether they are negative or positive, and shall assume the responsibility for preparing final or partial reports, as well as for informing the relevant parties. To this end, the Principal Investigator shall give the Sponsor the clinical data obtained during the study and stipulated in the Protocol for preparing the final report.
		3. The Sponsor recognises the right of BIODONOSTIA, the Principal Investigator and the Centre to publish the results, and that the Sponsor should be informed in writing within at least forty five (45) of any action taken to publish, disseminate or present the information, where any action is understood as referring to any acceptance, including but not limited to lectures, dissertations, abstracts for congresses, scientific or educational articles, or any mode of communication utilised with regard to the Study. If within said period no reply is received from the Sponsor, the proposed publication or communication shall be regarded as approved.
	3. Confidentiality and protection of data
		1. The parties to this Contract undertake to treat the documents, information, results and data relating to the Study as confidential and secret, ensuring restricted circulation of said information, and shall be responsible for ensuring that said obligation is complied with by all the persons that require access to same in accordance with the agreements in this Contract. The exceptions to said undertaking of confidentiality include information that: (i) the receiving party knew at the time the disclosing party when it was received; (ii) is currently or later shall become known or generally available information and where said process is not the result of an act or omission of the receiving party; (iii) disclosure is required by law or order of a court, tribunal or the administration.
		2. The parties to the contract shall undertake to ensure that the personal data of the participants in the study shall be treated in accordance with the provisions established in Law 15/1999, of 13 December, on protection of personal data and the regulations implementing same, Law 2/2004, of 25 February, on publicly owned personal data files and on the creation of the Basque Agency of Data Protection, as well as Law 41/2002, of 14 November, on the autonomy of the patient and rights and obligations with regard to clinical information and documentation, and special care shall be taken to ensure that any personal data of the patients that is communicated to the Sponsor shall be previously disassociated in such a way that the information that is obtained from same cannot be associated with with an identified or identifiable person.
1. **Participants**
	1. Sponsor

Contact details:

 Organisation: *(add name of company)*

 Address: *(complete address of company)*

 Contact person: *(first name and surname)*

 Telephone number: *(telephone number)*

 Electronic mail: *(electronic mail address)*

If any change is made with regard to the person responsible for the Study by the Sponsor, said change should be reported by the Sponsor to BIODONOSTIA.

* 1. Principal Investigator:

The Principal Investigator shall oversee and ensure that all the participants in the study, and especially the collaborators, shall faithfully comply with this contract and the annexes of same, and that they have been sufficiently informed of same.

* 1. Collaborators
		1. The Principal Investigator shall be responsible for proposing the members of the research team and the support staff for the Study. In this regard, the Principal Investigator has proposed the following persons as collaborative researchers:
		+ Mr/Ms. *(complete name of collaborator)*
		+ Mr/Ms. *(complete name of collaborator)*
		+ Mr/Ms. *(complete name of collaborator)*
		1. Pharmacy:
		+ Mr/Ms. *(complete name of collaborator)*
		1. Collaboration services:
* Mr/Ms. *(complete name of collaborator)*
* Mr/Ms. *(complete name of collaborator)*
	1. Other staff

BIODONOSTIA may contract the other professionals and material resources required to conduct the study, according to the needs indicated by the Principal Investigator, the Centre and the Sponsor.

* 1. BIODONOSTIA

BIODONOSTIA shall be responsible for the financial and administrative management to support the Centre and the Principal Investigator in the correct implementation of the study.

* 1. Research Organisation *(Optional clause)*

To carry out the Study, the Sponsor has contracted the services of *(add company name)*, which is a contract research organisation with business address at *(add complete address )* and TIN *(add tax identification number).* (hereinafter, the “**CRO**”), to carry out the following functions:

* *(add function to be carried out by the CRO)*.
* (*add function to be carried out by the CRO)*.
* (*add function to be carried out by the CRO)*.
	1. Monitor

The Sponsor has appointed the following company staff member as monitor *(add name of company)* with TIN *(add tax identification number).* (hereinafter, the “**Monitor**”). If the monitor is changed, the Sponsor shall notify BIODONOSTIA.

1. **Place of study.**
	1. The Study should be conducted at *(name of Centre and Service/Unit, where applicable)*.
	2. The Centre shall make available for the purposes of conducting the study whatever human resources are used in its daily activities.
2. **Supply of heath product, equipment and special material for the Trial**
	1. The Sponsor shall supply the health product for the Study at no charge.
	2. If special equipment or materials are required for the Study, the Sponsor undertakes to facilitate them at no cost whatsoever to the centre. At the end of the Study, any surplus special equipment or materials supplied shall be returned to the Sponsor.
3. **Insurance**

If performance of the Study requires any type of invasive procedure or implies a greater risk to the patient than that corresponding to habitual clinical practice, the Sponsor certifies that he has taken out a civil liability policy with the company *(add name of insurance company)* with number: *(add policy number)* that should cover all losses and damages that might be caused by their participation in the Study, as well as the responsibilities of the Sponsor, the Centre, BIODONOSTIA and the Research Team.

1. **Financial aspects (Annexe II).**

The financial aspects shall be described in the financial memorandum that appears in Annexe II of the contract, as an inseparable part thereof.

* 1. Costs of management of the contract.

The sum of *(add figure in accordance with table of rates)* € + VAT is established, payable for management of the contract, and payment shall be made against the presentation of the relevant invoice, in parallel with management of the contract. (Table I of ANNEXE II).

* 1. Costs of execution of the study.

The sum of *(sum per concluded patient)* €, plus tax, shall be made effective per concluded patient. (Table II of ANNEXE II). All of which includes the following items

* Payment for work carried out by health professionals and other structural resources of the centre, stratified as visits made or patients with monitoring concluded.
* Direct special costs, including any expenses that were not produced from not having participated in the Study.
	1. BIODONOSTIA shall invoice the Sponsor for all the costs incurred from the study, except for payment of the research team (if not expressly indicated otherwise by the Principal Investigator) and the funds shall be distributed in the following manner (Table IV of Annexe II)
		+ - 10% of the total of the Study shall be allocated to BIODONOSTIA to defray the expenses caused by managing the execution of same.
			- 27% shall be allocated to the research centre to promote the research.
			- 63% shall be allocated to the research team.

*Option 1 (In the event that the managing body invoices the part of the research team) If the Principal Investigator so instructs, said amount shall be paid directly to Biodonostia to be reinvested in R+D+i activities of the Researcher or Research Team* .

*Option 2:* *Payment to the Research Team shall be made directly by the Sponsor into his/her account provided by same.*  (Table IIII of Annexe III).

* *Nombre completo:*
* *CIF:*
* *Nº de Cuenta:*
	+ - * The special costs shall be earmarked for the centre to defray the corresponding costs, as well as for BIODONOSTIA to defray the management expenses.
	1. Methods of payment
		1. Calculation of the level of execution of the study for the purposes of invoicing shall be reported to the BIODONOSTIA by the Sponsor and in parallel by the Principal Investigator, so that BIODONOSTIA may issue the appropriate invoices after contrasting the data.
		2. The Sponsor shall effect payment of the invoice issued by BIODONOSTIA within thirty (30) days dating from the date of issue of each invoice, in the account number given by the foundation.
1. **Obligations**
	1. The Sponsor shall be responsible for obtaining the necessary permits from the CEIC prior to commencement of the Study.
	2. The Principal Investigator shall conduct the Study in strict compliance with the Protocol, which establishes the activities and tasks that should be commenced, performed and monitored with due diligence.
	3. The Centre shall facilitate provision of the work of the professionals who participate in the Study, in particular that of the Principal Investigator and other research staff.
	4. BIODONOSTIA shall be responsible for the financial and administrative management of the funds corresponding to the centre and, in the event that the Principal Investigator so instructs, for those corresponding to the research team.
2. **Suspension of Study**
	1. The Study may be suspended in the following circumstances:
		1. As a result of a breach of the obligations borne by the Parties in accordance with this contract, if said breach is not amended by the breaching Party within 15 days, calculated from reception of a written notification in which the complying Party demands compliance with said obligations.
		2. If compliance with the Protocol is deficient or the data is repeatedly inexact or incomplete.
		3. By mutual agreement between the contracting parties, which should be established in writing.
	2. In the event of early termination of the Study, the Sponsor shall only pay the provisions made up to the date of the early termination.
3. **Applicable legal system and jurisdiction**
	1. The provisions of this Contract shall be regulated and interpreted in accordance with the applicable legislation on this type of study
	2. In the event of any dispute over the interpretation or fulfilment of this Contract, the parties, with express waiver of any other jurisdiction to which they might be entitled, submit to the courts of Vitoria-Gasteiz, offices of Osakidetza.

And in accordance with all the foregoing, in witness whereof, they enter into this contract in quadruplicate.

**ASOCIACIÓN INSTITUTO BIODONOSTIA:**                                                          **the PROMOTOR:**

Mr. Julio Arrizabalaga *(name of legal representative of the*  Sponsor)

And accepting the undertaking of the terms and conditions that appear in this contract:

**the Centre:                                                             Principal Investigator:**

*Mr. José Manuel Ladrón de Guevara**(name of the Principal Investigator)*

**Annexe I: Protocol**

**Consult in separate document**

**Annexe II: Financial memorandum**

**Title of study:** *(complete title of study)*

**Code:** *(add code assigned by Sponsor)*

**Centre:** *(name of Centre)*

**No. of patients estimated for this centre:** *(number of participants in the study)*

**No. of participating centres in the Autonomous Community of the Basque Country:** *(number of participating centres in the autonomous community of the Basque Country)*

**Table 1, Costs of management of the contract.**

|  |  |
| --- | --- |
| BIODONOSTIA |  |
|  VAT  |   |
| **TOTAL** |  |

**Table II. Costs of execution of the study.**

|  |  |  |  |
| --- | --- | --- | --- |
| **DESCRIPTION**  | **AMOUNT FOR VISIT €** **A** | **SPECIAL TESTS €****(B)** |  |
|   |
| Visit 1 |   |   |  |
| Visit 2 |   |   |  |
| Final Visit |   |   |  |
| Others  |   |   |  |
| **TOTAL FOR COMPLETE PATIENT** |  |  | ***TOTAL\*******(A) +(B)*** |
| *(\*) Total execution costs per concluded patient should appear in section 7.1.2 of the contract* |
| **TOTAL STUDY** | *TOTAL (A) +(B) x No. of ESTIMATED PATIENTS* |

**Table III Direct Special Costs per patient**

|  |  |  |  |
| --- | --- | --- | --- |
| **SPECIAL** **TESTS (B)** | **UNITS** **(Patient)**  | **UNIT AMOUNT\*** | **TOTAL PATIENT** |
|  |   |   |  |
|  |  |  |  |
|  |  |  |  |

*(\*) The price of the tests includes the percentage corresponding to BIODONOSTIA.*

**Table IV. Breakdown of Amount per patient.**

|  |
| --- |
| **BREAKDOWN OF AMOUNT PER VISIT****(Table II column A)** |
| A. Research Team | 63% |  |
| B. Centre | 27% |  |
| C. BIODONOSTIA | 10% |  |
| TOTAL |  |
| **BREAKDOWN OF AMOUNT FOR SPECIAL TESTS****(Table II column B)** |
| 1. Centre-Cost of test
 | 90% |  |
| B. Management costs - BIODONOSTIA | 10% |  |
|  |  |  |  |

**Invoice details:**

Taxes payable in accordance with current legislation shall be applied to these amounts.

For the purposes of issuing invoices by Biodonostia, the following should be recorded:

* Name of promoting company: *(add complete name of promoting company)*
* Name of the company making payment: *(name of company)*
* Tax address: *(complete address of company)*
* TIN: *(tax identification code)*
* Contact person: *(name and surname of person responsible)*
* Telephone number *(telephone number)*
* E-mail address:*(electronic mail address)*

**Annexe III: Powers to sign on behalf of the Sponsor**