# Sole agreement

**HEALTH Establishment, CENTRE OR CARE HOME / COMPANY**

**concerning the implementation of the protocol for**

**commercial research involving the human person, clinical trials on medicinal products or clinical investigations of medical devices**

**OR PERFORMANCE STUDIES OF IN VITRO DIAGNOSTIC MEDICAL DEVICES**

**Clinical Trial No.**

**EudraCt / CTIS / EU CTR no…….. or ID-RCB no………**

***Coordinating Establishment Version***

BETWEEN THE UNDERSIGNED:

of the one part,

**The** …………………. health establishment, centre or care home entered in the FINESS (National File of Health and Business Establishments) under no. …………….., whose SIRET (French corporate ID) code is …………………. and whose registered office is at……………………….., represented by …………………….. and hereafter referred to as the “**Coordinating Establishment**“;

**OR, where appropriate,**

The State (Ministry of Defence), represented by [doctor, pharmacist, other] (rank) ....................,

Function (chief medical officer, commander, ...) of the agency of the armed forces health service (Armed Forces Training Hospital (HIA), other) .............

……………………..Address………………………………

and hereinafter referred to as the "**Coordinating Establishment**,"

**of the other part,**

The company …………………………………………… (juridical form of the Contractor)….. entered in the Companies' Register (RCS) of ………. under number …………..,

*whose registered office is at* …………………………………………………… *represented by its ……… (position of legal representative), Mr. ………………… (name of legal representative), duly empowered to sign this agreement, and hereafter referred to as the “****Company****“;*

**OR where appropriate, /AND**

**The company** ………………. whose registered office is at ……………… represented by its ……… (position of legal representative), Mr. ………………… (name of legal representative), fully or partially empowered to execute [to sign] this agreement in the name and on behalf of the Company and hereafter referred to as the “CRO“ (Contract Research Organisation).

**and, where appropriate,**

The third-party structure………………… (Juridical form of Third-party structure), represented by its ……….… (position of legal representative), Mr. .………… (name of legal representative), and hereafter referred to as the “**third-party structure**“.

The Coordinating Establishment, the Company or the CRO acting on behalf and in representation of the Company and, where appropriate, the Third-party structure, are hereafter referred to individually as the “Party“ or collectively as the “Parties“.

**Having considered:**

The (EU) Regulation No. 536/2014 of the European Parliament and the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC;

The (EU) Regulation No. 2016/679 of the European Parliament and the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation);

Regulations (EU) No. 2017/745 and 2017/746 of the European Parliament and of the Council of 5 April 2017 on medical devices;

The French Public Health Code, in particular Articles L. 1121-16-1 and, L. 1124-1, L. 1125-15 and R. 1121-3-1;

The French Civil Code, in particular Articles 1367 and 1112-2;

The French Defence Code, in particular Articles R. 3232-11 to R. 3232-14;

Law no. 78-17 of 6 January 1978 on data processing, data files and individual liberties;

Codes of ethics for the health professions;

Decree no. 2008-967 of 16 September 2008 laying down the ethical standards specific to military practitioners;

The decision of the general director of the French Agency for the Safety of Health Products of 24 November 2006 setting the rules of clinical good practice for biomedical research involving medicinal products for human use;

The approvals, authorisations and certificates required for conducting the Research;

[if applicable] The agreement of the Central Directorate of the Armed Forces Health Service (*Direction centrale du service de santé des armées* (DCSSA)) or the Directorate for Education, Research and Innovation (*Direction de la formation, de la recherche et de l'innovation* (DFRI)) dated ....... ;

WHEREAS:

The Company has decided to conduct the research or the clinical investigation governed by the Protocol entitled and referenced as follows: \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_, hereafter referred to as the “Research“. The Protocol and its endorsements are hereafter referred to as the “Protocol“.

The Research:

* will be conducted in the Coordinating Establishment signatory of this agreement;

[For trials under the regime of Directive 2001/20/EC of the European Parliament and the Council of 4 April 2001, and therefore of Act No. 2012-300 of 5 March 2012 on research involving the human person, known as the JardéAct]:

* [if the authorisation is in course of being obtained] has been filed with the French National Agency for the Safety of Medications and Health Products (ANSM) to request authorisation, and the number will be provided by the Company to the coordinating Establishment before the opening of the centres;
* [if the authorisation has been obtained] is registered under no. \_ \_ \_ \_ \_ \_ \_\_ \_ \_ \_ \_ \_ \_ and authorised on\_ \_ \_ \_ \_ \_ \_\_ \_ \_ \_ \_ \_ \_ by the ANSM;
* [if the opinion is in course of being obtained] has been submitted to the Committee for Protection of Persons for (*state the region*)\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ and the opinion will be provided by the Company to the Coordinating Establishment before the opening of the centres;
* [if the opinion has been obtained] has been submitted to the Committee for Protection of Persons for (*state the region*)\_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_ \_, a favourable opinion having been received on\_ \_ \_ \_ \_\_ \_ \_ \_ \_ \_ ;

[For clinical trials on medicinal products under the European Regulation (EU) No 536/2014 of the European Parliament and the Council of 16 April 2014];

or

[For clinical investigations of medical devices referred to in Article 1 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017];

or

[For studies of the performance of in vitro diagnostic medical devices referred to in Article 1 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017]:

* [if the authorisation is in the course of being obtained] has been filed for authorisation in France through the EU portal and the number will be provided by the Company to the Coordinating Establishment prior to the opening of the centres,
* [if the authorisation has been obtained] is registered under no. \_ \_ \_ \_ \_ \_ \_\_ \_ \_ \_ \_ \_ \_ and authorised in France on\_ \_ \_ \_ \_ \_ \_\_ \_ \_ \_ \_ \_ \_,
* is for a provisional period of \_ \_ \_ \_ \_ \_ \_months, from \_ \_ \_ \_ \_ \_ \_\_ \_ \_ \_ \_(provisional date for commencing the Research declared to the ANSM);
* is covered by an insurance policy with \_ \_ \_ \_ \_ \_ \_ \_ \_ , policy no.\_ \_ \_ \_ ;
* concerns the provisional recruitment of [*state the number of patients*]patients in the Coordinating Establishment.

The Coordinating Establishment signatory of this agreement has the knowledge, experience, availability and material capability to conduct the Research referenced above. It must be able within the time allowed to recruit the number of patients required; according to the criteria for inclusion in the Protocol; and be able to conduct the Research in its premises.

Any item, information, document, product or equipment provided by the Company under this agreement may only be used for the purposes of the Research subject to this agreement and in accordance with the Research Protocol.

**IT IS HEREBY AGREED AS FOLLOWS:**

## CLAUSE 1: OBJECT

This agreement is intended to determine the assignments conducted by the Coordinating Establishment for the Company, pursuant to the Research, the conditions governing it and the additional costs incurred, hereafter referred to as the “Costs“ and “Additional costs“ of the Research.

The assignments include:

* provision by the Coordinating Establishment of the human, material and technical resources required for realisation of the Protocol;
* completion of the tasks required for conducting the Research in terms of clinical investigation;
* completion of the clinical investigation.

The Company shall not conclude any other remunerated contract with the Coordinating Investigator for realisation of the assignments under this agreement.

## CLAUSE 2: DEFINITIONS

In the sense of this agreement,

The Additional costs are those relating to financial responsibility for the patient or the healthy volunteer required for realisation of the Protocol. They concern the acts required for the Research, in addition to those referred to in the clinical Good Practice recommendations approved by the High Authority for Health (HAS) for the financial responsibility concerned, if any, and which cannot be invoiced to the French Social Security Health Insurer or the patient.

The Costs are any other additional costs relating to the realisation of the Protocol, including any investigation required for the Research and the administration and logistics associated therewith.

Coordinating Establishment: establishment, care home, health centre or agency of the armed forces health service concluding the agreement and undertaking, in consultation with the investigator, to approve the list of Additional costs proposed by the Company or to make counter-proposals based on the investigator's expertise.

The list of the Additional costs and Costs, and their evaluation, are identical for all the Establishments associated with the Research, in proportion to the tasks effected.

Associated Establishment: establishment, care home, health centre or agency of the armed forces health service participating in the Research by the inclusion of patients and the provision of one or more investigators or other research personnel.

Coordinating investigator: the investigator designated as such by the sponsor in accordance with Article L. 1121-1 of the French Public Health Code or in accordance with Annexe XV, Chapter II, Section 3.1.3. of Regulation (EU) 2017/745 for clinical investigations.

Result(s): means any document, data, information, report, analysis, digital file, database or work resulting from the Research or this agreement, whatever their form, medium or means of writing.

## CLAUSE 3: PARTIES' CONTACT DETAILS / CORRESPONDENCE

Any letter, despatch or notification resulting from the application of this agreement shall be sent for the attention of the administrative and scientific contacts of each Party, as set out in appendix 1.

No endorsement will be required for any change of administrative and/or scientific contact during the Research, provided that the other Party(-ies) is/are informed thereof in advance in writing.

## CLAUSE 4: UNDERTAKINGS OF COORDINATING ESTABLISHMENT

The Coordinating Establishment undertakes to comply with all the statutory and regulatory provisions applicable on French territory, in this agreement and the Research protocol.

The Coordinating Establishment shall ensure compliance with the provisions of this agreement and the Research Protocol by all the Research personnel under its direction and control.

The Coordinating Establishment shall ensure the due organisation and execution of the tasks imposed under this agreement, including the due progress of the Research conducted under the responsibility of its investigator.

The Coordinating Establishment shall indemnify the Company against any damage (including fire or water damage) incurred by the patients or personnel participating in the Research, or by any medication, product, material or equipment, in the premises provided for conducting the Research, by reason of its activity, equipment or personnel.

This agreement is concluded in consideration of the Coordinating Establishment, which may not subcontract the assignments entrusted to it, without the prior written agreement of the Company. In the event of authorised subcontracting, the Coordinating Establishment shall be liable for any breach on the part of its subcontractors vis-à-vis the other Parties.

## CLAUSE 5: [where appropriate] UNDERTAKINGS OF THIRD-PARTY STRUCTURE

The Third-party Structure undertakes to comply with all the statutory and regulatory provisions applicable on French territory.

The Third-party structure undertakes to take all reasonable care and professional diligence required for the performance of the tasks entrusted to it under this agreement, the Protocol and in accordance with existing norms and standards.

The Third-party Structure undertakes throughout the period of the Research to provide all the resources required for the performance of its assignments, as defined in appendix 4 and, where appropriate, in Appendix 2.

The Third-party Structure accordingly declares that it has taken out French civil liability insurance with a reputedly solvent insurer, covering the financial consequences of its professional and civil liability for any direct or indirect damage it may cause in or during the execution of this contract.

This agreement is concluded in consideration of the Third-party structure, which may not subcontract the assignments entrusted to it, without the prior written agreement of the Company. In the event of authorised subcontracting, the Third-party structure shall be liable for any breach on the part of its subcontractors vis-à-vis the other Parties.

## CLAUSE 6: UNDERTAKINGS OF THE COMPANY

The Company undertakes to comply with all the statutory and regulatory provisions applicable on French territory.

* In particular, it provides the management of the Coordinating Institution with the following documents and information: Protocol (in French or English), summary/synopsis of the Protocol in French, [copy of the delegation mandate in the case of monitoring by a CRO], regulatory documents (proof of submission to CTIS or decision if opinion/authorisation obtained, ANSM authorisation, IRB opinion, insurance certificate), name and title of the person signing the agreement, wording and address for sending invoices.
* It provides the Coordinating Establishment with the proposed list of the Costs, Additional costs and Consideration.
* It informs the Coordinating Establishment of any modification of the Research period in relation to the period initially adopted, as referred to in the Preamble to this agreement.
* It pays the Costs and Additional costs associated with the Research, as fixed in an appendix to this agreement.
* [If appropriate] It undertakes to make the various applications for authorisation or declaration of activities, transfer or import-export relating to the use of products or elements of the human body in accordance with appendix 6, if applicable.

## CLAUSE 7: INVOICING AND PAYMENT PROCEDURES

The fixed costs, as defined in appendix 2, are payable by the Company as from signature of this agreement.

The other costs, as defined and to be detailed in appendix 2, are subsequently paid by the Company on presentation of a receipt or invoice from the Coordinating Establishment, based on information shared by the Company and the investigator and transmitted to the Establishment (number of patients selected, number of patients included, examinations and treatment carried out and data collected).

The Company, together with the investigator, shall inform the Coordinating Establishment of the end of the Research and provide the information required for final calculation of the additional costs due.

## CLAUSE 8: CONSIDERATION

In addition to the Costs and Additional costs, the Company may decide to pay consideration to the Coordinating Establishment or, where appropriate, the Third-party structure, for the expected quality of data resulting from the Research. Such consideration does not cover the assignments of the Coordinating Establishment, already included under the Costs and Additional costs.

## CLAUSE 9: RIGHTS IN THE RESULTS, CONFIDENTIALITY, PUBLICATION

### 9.1 Confidentiality

The Coordinating Establishment or, where appropriate, the Third-party structure, shall treat any information or document received from the Company under this agreement and the Results of the Research as strictly confidential.

This obligation covers any information and communication media provided by the Company or on its behalf, including information and data concerning any product which:

* was not already in the possession of the Coordinating Establishment or investigator and/or Third-party Structure before their disclosure by the Company;
* was not in the public domain, except for information becoming accessible to the public without any fault by the Coordinating Establishment or investigator and/or Third-party structure or by any person working in connection with the Research;
* was not communicated to the Coordinating Establishment or investigator and/or Third-party Structure by another person entitled to disclose it.

Confidential information and documents also include the clauses of this agreement, the Protocol and any information and data from the Research, including observation records and any information therein.

Confidential information may be disclosed, however, with the written agreement of the Company or on request by the competent authorities, or in publications as defined below.

For its part, the Company shall treat as strictly confidential any information relating to the Coordinating Establishment or investigator and/or Third-party structure, received pursuant to the Research under this agreement.

The confidentiality undertaking of the Parties applies throughout the term of this agreement and for as long as the confidential data is not in the public domain.

In accordance with article 1112-2 of the French Civil Code, the information is considered confidential, regardless of the date of communication (and in particular in the event of communication prior to the conclusion of this agreement, during its negotiation, within the framework of its performance, following its termination or during any related dispute).

[If a Research Establishment is an agency of the armed forces health service] The Company and/or the Third-party Structure and/or the Coordinating Establishment shall not be privy to classified information of national defence interest, unless expressly decided by the military authority.

[If a Research Establishment is an agency of the armed forces health service] The Company and/or the Third-party Structure and/or the Coordinating Establishment acknowledge that they are aware of the legislative and regulatory provisions relating to respect for national defence secrecy and undertake to keep secret all classified information of interest to national defence which they may come to know as a result of the activities carried out under this agreement.

### 9.2 Intellectual property rights

The Results of the Research are the sole and exclusive property of the Company, which may exploit them without restraint.

The Company may, directly or indirectly in its own or any other name and on its behalf, apply for any patent over the results of the Research or wholly or partly incorporate them and, more generally, thereby protect the results of the Research.

The Coordinating Establishment and/or the Third-party Structure shall take any steps required to ensure that ownership of the Results of the Research be conferred on the Company.

Any intellectual property right held by a Party before the date of signature of this agreement shall remain its property, without this agreement affecting any such right.

### 9.3 Publication

The Coordinating Establishment and investigator and/or Third-party structure expressly agree that the Results of the Research be published exclusively under the coordination of the Company, so as to include the Results of all the participating centres in the publication.

In accordance with article R. 5121-13 of the French Public Health Code, the Research may not be published or communicated, orally or in writing, by the Coordinating Establishment or investigator and/or Third-party Structure, without the prior written agreement of the Company.

Requests for publication or communication must be made to the administrative and scientific contacts of the Company by receipted recorded delivery letter. The Company undertakes to respond thereto as soon as possible.

### 9.4 Use of name and/or logo

The logos and/or names of the Parties shall not be used outside the formalities required for conducting the Research, without the written agreement of the other Party. Nonetheless, publication of the names or logos will be possible when required pursuant to regulations.

### 9.5 Audit

Provided that they have been informed of the identity of the auditor, the dates and ambit of the audit at least fifteen days before it is carried out on the site, the Coordinating Establishment and the Investigator undertake to assist the Company or its agent in relation to any audit or inspection, on the Research done under this agreement, in accordance with all the legal provisions governing clinical Good Practice.

## CLAUSE 10: EFFECTIVE DATE - TERM - TERMINATION OF AGREEMENT

This agreement, of which the appendices are an integral part, shall take effect from its date of last signature by the Parties. It shall bind the Parties until the end of the Research, as defined in the last paragraph of clause 7 of this agreement.

In relation to the Research, any opening of new centres, in an associated establishment, care home or health centre, shall be done on the basis of this agreement.

This agreement may be terminated by either Party before its expiry date, by receipted recorded delivery letter, should any technical, methodological or scientific event compromise the continuation of the Research. It shall be automatically terminated where the competent authority refuses to allow the Research.

The Research period may be modified by prior written agreement between the Parties without any endorsement.

In the event of premature interruption:

* the variable costs incurred by the Coordinating Establishment are payable by the Company, *pro rata* to the work done by the date of termination of the agreement;
* the fixed costs, referred to in appendix 2 of this agreement, are payable in any event, including in default of inclusion in the object of the research.

In the event of serious or deliberately repeated breach, during the Research, of quality control or audit, the Company or the Coordinating Establishment shall be informed without delay and may automatically terminate this Agreement, without notice or compensation.

This agreement may be terminated by either Party for breach by the other of any obligation contained herein. Such termination shall become effective three months after despatch by the complainant Party, by receipted recorded delivery letter setting out the grounds for the complaint, the same having no effect, provided that, within this period, the defaulting Party has not complied with its obligations or provided evidence of impediment due to an event of f*orce majeure*.

[If a Research Establishment is an agency of the armed forces health service] Furthermore, if defence imperatives so require or in the event of a serious health threat or crisis requiring the assistance of the armed forces health service, the State (the Ministry of the Armed Forces) may terminate the agreement without notice and without the other Party being entitled to claim any compensation.

## CLAUSE 11: ANTI-CORRUPTION

The Coordinating Investigator expressly undertakes during the period of execution of the agreement to comply with the law and regulations in force, including the provisions relating to the prevention of corruption.

The Coordinating Investigator certifies that he has not, directly or indirectly, proposed or authorised any act with a view to payment or transfer of anything of value in order to exercise undue influence on any public agent or individual, nor will do so in the future.

The Coordinating Investigator declares that he is under no impediment for conducting the Research.

In accordance with article L. 1453-1 of the French Public Health Code, the Company is bound to make public the existence of the agreement and its benefits. In this respect, and in order to ensure the traceability of the benefits and remunerations granted, the Coordinating Establishment and, where applicable, the Third-party Structure shall transmit to the Company all the information they have knowledge of which makes it possible to identify any indirect and final beneficiaries, in accordance with article R. 1453-3 of the French Public Health Code.

The Parties declare that the Research will be carried out in compliance with and in application of the fundamental principles of ethics and all applicable French or European regulations on fight against corruption.

## CLAUSE 11 BIS: PROCESSING OF PERSONAL DATA

The Parties undertake to comply with the regulations in force applicable to the processing of personal data and, in particular, (EU) Regulation No. 2016/679 of the European Parliament and the Council of 27 April 2016 (hereinafter, the "General Data Protection Regulation" (GDPR) and Act No. 78-17 of 6 January 1978 on Information Technology, Data Files and Civil Liberties, as amended (hereinafter, the "Amended Data Protection Act").

### 11 BIS.1 Processing of personal data relating to the management of this agreement and relations and contacts between the Parties

In order to ensure the management of this Agreement and the relations and contacts between them, the Parties need to, each on its own behalf, process the personal data of the natural persons signing and approving this Agreement as well as the personal data of the personnel of the other Party, in the capacity of controller, in the meaning of Article 4.7 of the General Data Protection Regulation.

Such processing of data is necessary for the purposes of the legitimate interests (in terms of management, organisation and monitoring) pursued by each Party or it is a legal obligation to which the Parties are subject.

The personal data of natural persons signing and approving this agreement and of the personnel of the Parties concerned by this processing can be accessed by contacting the Data Protection Officer (DPO) of each of the Parties, when the Parties have appointed a DPO, and, failing that, by contacting the relevant department (the contacts are listed in appendix I to this agreement). The data will be kept by the Parties for the time necessary for the purposes pursued, in accordance with the regulations in force.

The natural persons signing and approving this agreement as well as the personnel of the Parties concerned by this processing have a right of access, rectification and erasure of data, a right to restriction of processing and a right to object to processing. These rights may be exercised directly with each of the Parties.

The natural persons signing and approving this agreement and the personnel of the Parties concerned by such processing operations may at any time lodge a complaint with a supervisory authority, in particular in the Member State where they normally reside, where they work or where they believe that a breach of the regulations has occurred.

Each Party shall provide the data subjects with information in accordance with the provisions of Article 13 *et seq.* of the General Data Protection Regulation, including the contact details where they can exercise their rights.

### 11 BIS.2 Processing of personal data relating to the Coordinating Investigator

The personal data relating to the Coordinating Investigator are processed by the Company for the purposes of setting up and carrying out the Research, as well as complying with the Company's legal obligations in connection with the transparency of links under Article L. 1453-1 of the French Public Health Code. The personal data relating to the Coordinating Investigator may also be used for other processing of personal data by the Company and relating to the management of human resources and training.

The Coordinating Investigator has, as the case may be, a right of access, rectification and erasure of data, a right to restriction of processing and a right to object to processing of his/her data.

The Company shall provide the Coordinating Investigator with information in accordance with the provisions of Article 13 et seq. of the General Data Protection Regulation, including the contact details where the Coordinating Investigator can exercise his/her rights.

### 11 BIS.3 Roles and obligations of the Parties with regard to the processing of personal data in the context of conducting the Research

In the framework of the performance of the Research, the Company acts as the controller in the meaning of Article 4.7 of the General Data Protection Regulation.

The Coordinating Establishment and, where applicable, the Third-party Structure, act as processors, in the meaning of Article 4.8 of the General Data Protection Regulation, on behalf of the Company.

In this respect, the Parties undertake to comply with the provisions set out in Appendix 3 to this agreement, in the framework of ...................................................................

## CLAUSE 12: DISPUTES

This agreement is subject to French law and may be signed in electronic form in accordance with Article 1367 of the French Civil Code.

In the event of any dispute relating to the interpretation or execution of this agreement, the Parties shall endeavour to negotiate a settlement of their differences.

In the event of failure to reach agreement, the territorially competent court will be that for the registered office of the Coordinating Establishment where the Research is carried out.

## CLAUSE 13: APPENDICES

The following appendices are considered as an integral part of the contract:

* Appendix 1 – list of the contacts of the Company, the Coordinating Establishment and, where appropriate, the Third-party structure and their contact details.
* Appendix 2 – procedure for calculating the costs and additional costs;
* Appendix 3 - clauses between controllers and processors in the meaning of Article 28 of the General Data Protection Regulation.
* Appendix 4 [optional] – consideration for conducting the Research;
* Appendix 5 [optional] – clauses on the rpovision of materials or equipement.
* Appendix 6 [optional] – Clauses on the provision of biological resources.

Signed in \_ \_ \_ \_ \_ \_, on \_ \_ \_ \_ \_ \_ \_

In X original counterparts.

|  |  |
| --- | --- |
| Per pro/ the Coordinating Establishment  [where appropriate]  Rank Name First name  Chief Medical Officer of the HIA | Per pro / the Company or Per pro/ the CRO, representing the Company |
| Per pro/ the legal representative of the Third-party Structure,  *(where appropriate)* |  |

Stamp of the Coordinating Investigator:

 NAME\_ \_ \_ \_ \_ \_ \_(RPPS - health professionals' registration - no.)\_ \_ \_ \_ \_ \_ STATUS\_ \_ in the \_ \_ \_ \_ \_ Department/Centre of the \_ \_ \_ \_ \_ \_ health establishment.

OR

Rank

Name First name

Title

*"I have read and understood this Agreement"*

|  |
| --- |
|  |

|  |
| --- |
| Appendix 1 |
| List and contact details of contacts within the Parties [Healthcare establishment, Company and Third-party Structure (if applicable)] |

|  |
| --- |
| **The Primary Contacts at the coordinating healthcare institution for any questions concerning the Trial are as follows:** |
| Scientific Contact, who is responsible in particular for all scientific questions relating to the conducting of the Research: |
| **Name**  **Title:** Principal Investigator  **Address:**  **Email:**  **Telephone number:** |
| Administrative Contact, who is responsible for all matters relating to the performance of this agreement: |
| **Name:**  **Title:**  **Address:**  **Email:**  **Telephone number:** |
| Administrative Contact, who is responsible for all matters relating to the performance of this agreement (if applicable): |
| **Name:**  **Title:**  **Address:**  **Email:**  **Telephone number:** |
| Administrative contact, who is responsible for all matters relating to the processing of personal data (Data Protection Officer): |
| **Name:**  **Title:**  **Address:**  **Email:**  **Telephone number:** |
| **The Company’s primary contacts, or those for the CRO acting on behalf of and representing the Company, for any question concerning the Trial are as follows:** |
| Scientific Contact, who is responsible in particular for all scientific questions concerning the conducting of the Trial: |
| **Name:**  **Title:**  **Address:**  **Email:**  **Telephone number:** |
| Administrative Contact, who is responsible for all matters relating to the performance of this agreement: |
| **Name:**  **Title:**  **Address:**  **Email:**  **Telephone number:** |
| Administrative Contact, who is responsible for all matters relating to the performance of this agreement (if applicable): |
| **Name:**  **Title:**  **Address:**  **Email:**  **Telephone number:** |
| Administrative contact, who is responsible for all matters relating to the processing of personal data:   * Contact for the Data Protection Officer (DPO): * Contact for exercising rights, if not the DPO: * Contact for further sub-processing, if not the DPO: * Contact for data breaches, if not the DPO:] |
| **Name:**  **Title:**  **Address:**  **Email:**  **Telephone number:** |
| **If applicable – The Third-Party Organisation’s contacts for any questions concerning the Trial are as follows:** |
| Scientific Contact, who is responsible in particular for all scientific questions concerning the conducting of the Trial (if applicable): |
| **Name:**  **Title:**  **Address:**  **Email:**  **Telephone number:** |
| Administrative Contact, who is responsible for all matters relating to the performance of this agreement: |
| **Name:**  **Title:**  **Address:**  **Email:**  **Telephone number:** |
| Administrative Contact, who is responsible in particular for all matters relating to invoicing under this agreement (if applicable): |
| **Name:**  **Title:**  **Address:**  **Email:**  **Telephone number:** |
| Administrative Contact, who is responsible for all matters relating to the processing of personal data (Data Protection Officer): |
| **Name:**  **Title:**  **Address:**  **Email:**  **Telephone number:** |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Appendix 2 | | | | | | |
| Classification of type of research for producing the matrix for the sole agreement for research for commercial purposes | | | | | | |
|  |  | |  |  |  |
| Definitions of various research typologies | | | | | | |
|  |  | |  |  |  |
| **items:** | | **Research complexity level:** | | | | |
| > 2 treatment arms | | **X** | | | | |
| Phase I/II or Research before CE marking | | **X** | | | | |
| Involving more than 2 Medico-technical Centres and/or departments and/or costly imaging plus pharmacy and investigation service | | **X** | | | | |
| With hospitalisation\* (>4hrs) and/or process effected with asepsis (sterile environment, theatre) | | **X** | | | | |
| Realisation of multiple PK and/or PD points and/or molecular screening | | **X** | | | | |
| Realisation in a costly care specialty (resuscitation, ophthalmology, intensive care, palliative care, surgery, burns, transplants, emergency services, oncology) | | **X** | | | | |
| Paediatric involvement | | **X** | | | | |
| \* if required by the Protocol for clinical investigations of medical devices | | | | | | |
|  |  | |  |  |  |
| **3 research "complexity" levels according to the number of crosses** | | | | | | |
| Level 1 | | | <2 | | | |
| Level 2 | | | 2 | | | |
| Level 3 | | | 3 and over | | | |

### Annexe 2.1

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Matrix for calculating the costs and additional costs incurred in carrying out commercial research** | | | |  |  |  |
|  |  |  |  |  |  |  |
| **Sponsor company** |  | | | | | |
| **CRO (if applicable)** |  | | | | | |
| **EudraCt/CTIS/EU CTR/ID-RCB research no.** |  | | | | | |
| **Name of coordinating or participating institution** |  | | | | | |
| **FINESS no.** |  | | | | | |
| **Investigator** |  | | | | | |
| **Division/Unit** |  | | | | | |
| **Expected number of patients for the centre:** |  |  |  |  |  |  |
| **Level of complexity of the research (see appendix 2):** |  | | | | | |
| **Grid version DD MM 2021 based on the protocol: version 00 of DD/MM/YYYY** |  | | | | | |
|  |  |  |  |  |  |  |
| **Evaluation based on:** | | | | | | |
|  |  |  |  |  |  |  |
| **Description of procedures and services carried out:** | **Occurrence limit** | **Cost or additional cost** | **Unit amount**  **Cost or additional cost (Excl. VAT) (add 40% for overseas territories)** | **Number of items per patient or for the centre** | **Total cost per patient or for the centre** **€ (Excl. VAT)** | **Total for the number of patients included in the centre or for the centre** **€ (Excl. VAT)** |
| **PRICES** | | | | | |  |
| **Fixed-rate administrative costs** | | | | | |  |
| **Administrative costs** Registration of the research, method for drawing up the agreement and the matrix, financial and administrative monitoring of the agreement, including amendments.  Rate applied per investigation centre and not per institution. If there are several investigation centres within the institution, several flat rates are invoiced. Invoiced as soon as the agreement is signed, even if it is the sponsor that decides to cancel before the research begins (if the matrix has already been drawn up). | Per institution | cost | €561,8 for the coordinating centre €224,72 for associated centres |  |  |  |
| **Additional costs for drawing up an amendment** ONLY if the substantial change to the matrix is linked to a radical change to the protocol. | Per institution | cost | €112,36 coordinating centre €56,18 associated centre |  |  |  |
| **Setting up research** Pre-selection of the centre, familiarisation with the protocol and its requirements, feasibility studies, contribution to the development of the matrix, response to questionnaires to check understanding of CBP, implementation meeting. Rate invoiced even if no patient included, invoiced as soon as the agreement is signed. | Per institution | cost | level 1 or extension: €337,08 level 2: €505,62 level 3: €674,16 |  |  |  |
| **Logistics costs** | | | | | |  |
| **Fixed-rate logistics costs** Telephone, secretarial services for scheduling appointments, office systems, small items, archiving of study documents and maintaining access to data. Contribution to hospital operating costs (premises, waste management, sterilisation, etc.), contribution to the depreciation of hospital investments, etc. (rate applicable to all patients included in the study, in proportion to the number of screenings and inclusions carried out, regardless of the number of visits made, including if additional visits and procedures are carried out over the entire duration of the study. *List visits* | Rate per patient and per visit | cost | level 1: €2,28 level 2: €3,37 level 3: €4,49 Add €5/patient/visit if external personnel are involved (excluding sponsor monitoring, CRO, CRA) |  |  |  |
| **Equipment maintenance costs**  To be priced on a pro rata basis based on the number of years | Per year of study | cost | 112,36 € |  |  |  |
| **RESEARCH TASKS** | | | | | |  |
| **Estimated medical time – €116,4/h** | | | | | |  |
| **Inclusion consultation or preselection visit** Information given to the patient by the doctor and obtaining consent.Level 1 research: 1 hour  Level 2 research: 1 hour 30 minutes  Level 3 research: 2 hours  Applicable in the event of failure at the preselection or inclusion visit  *List the visit* | Per patient | cost | level 1: €116,4 level 2: €174,6 level 3: €232,8 |  |  |  |
| **Consultation for Addendum to the information note/new safety information**  30 minutes, in the event of revision of the information note or new safety information | Per consent/patient | cost | 58,20 € |  |  |  |
| **Additional 45-minute informed consent consultation (during study**, pregnancy, genetics, etc.) | Per patient | cost | 87,30 € |  |  |  |
| **Phone follow-up** 15 minutes regardless of the type of research *List visits* | Per patient | cost | 29,10 € |  |  |  |
| **Medical time** Medical time over and above normal practice (training, specific examination) and not taken into account in the procedures carried out as part of the research. Per hour, pro rata.  *List visits* | Per patient | cost | 116,40 € |  |  |  |
| **Medical time** Familiarisation with the amendment to the protocol, 30 minutes | Per amendment | cost | 58,20 € |  |  |  |
| **Sponsor audit excluding pharmaceuticals (if <1 day)** From preparation to implementation of corrective measures (excluding pharmaceuticals. Specific pricing for research into medical devices). | Per centre | cost | 337,08 € |  |  |  |
| **Sponsor audit excluding pharmaceuticals (if >1 day)** From preparation to implementation of corrective measures (excluding pharmaceuticals. Specific pricing for research into medical devices). | Per centre | cost | 505,62 € |  |  |  |
| **Estimated CRA investigator time – €57,5/h** | | | | | |  |
| **CRA investigator training time** **Level 1 research:** 4 or 5 hours (1 hour for the paper CRF **or** 2 hours for the eCRF, 1 hour for reading the protocol, 1 hour for drafting procedures for the department, 1 hour for administrative management). **Level 2 research:** 5 or 6 hours (1 hour for the paper CRF, 2 hours for the eCRF, 2 hours for reading the protocol, 1 hour for drafting procedures for the department, 1 hour for administrative management). **Level 3 research:** 7 or 8 hours (1 hour for the paper CRF, 2 hours for the eCRF, 3 hours for reading the protocol, 2 hours for drafting procedures for the department, 1 hour for administrative management). | Per trained member of staff | cost | level 1: €230 or €287.5  level 2: €287.5 or €345  level 3: €402.5 or €460 |  |  |  |
| **CRA investigator time for monitoring with sponsor/CRO** Per day and per CRA monitor. Preparing patient records, availability, resolving queries (by averages and not by number of patient records). **Level 1 research:** 2.5 hours per monitoring visit. **Level 2 research:** 4 hours per monitoring visit. **Level 3 research:** 5 hours per monitoring visit. | Per day and per CRA monitor | cost | Level 1 research: €186.25 Level 2 research: €230 Level 3 research: €287.5 |  |  |  |
| **CRA investigator time for remote monitoring (audio-conf. telephone appointment) - 2 hours** | Per appointment | cost | 115,00 € |  |  |  |
| **CRA investigator time for screening patient visit** Preparing for visits: organisation and planning protocol procedures, hospital admissions, providing information for the patient on what will happen during the research visits in practice. Completing the CRF, including patient history, gathering source data, resolving queries. **Level 1:** 1 hour + 15 minutes for every 10 pages of CRF. **Level 2:** 2 hours + 15 minutes for every 5 pages of CRF (justification: changes to the care pathway resulting from the introduction of the Research). **Level 3:** 3 hours + 15 minutes for every 5 pages of CRF. Applicable if selection is unsuccessful  *List the visit* | Per visit | cost | level 1: €57,5  level 2: €115  level 3: €172,5 |  |  |  |
| **CRA investigator time for patient follow-up on site or by phone** Organisation of the visit (including organisation and planning of protocol procedures, hospital admissions, etc.), completing the CRF, resolution of queries, management of undesirable events, specify which with the help of the protocol. **Level 1:** 1 hour + 15 minutes for every 10 pages of CRF. **Level 2:** 2 hours + 15 minutes for every 5 pages of CRF. **Level 3:** 2 hours + 15 minutes for every 5 pages of CRF. *List visits* | Per visit | cost | level 1: €57,5 level 2: €115 level 3: €115 |  |  |  |
| **CRA investigator time for final visit or early exclusion** Preparing for the visits (including organisation and planning protocol procedures, hospital admissions, etc.), completing the CRF, resolving queries. **Level 1:** 1 hour + 15 minutes for every 10 pages of CRF. **Level 2:** 2 hours + 15 minutes for every 5 pages of CRF. **Level 3:** 2 hours + 15 minutes for every 5 pages of CRF. *List the visit* | Per visit | cost | level 1: €57,5 level 2: €115 level 3: €115 |  |  |  |
| **CRA investigator training time for questionnaires and patient logs -** 1 hour/protocol | Per trained member of staff | cost | 57,50 € |  |  |  |
| **CRA investigator time for managing self-questionnaires or carrying out and filling in patient questionnaires, setting up the questionnaire tablets, loading, helping with connection, checking, depositing in the department** - 15 minutes per patient (if paper) or 45 minutes (if electronic) - if > 5 self-questionnaires 30 minutes per patient (if paper) or 1 hour (if electronic) *List visits* | Per visit | cost | €14,37 if > 5 self-questionnaires: €28,75 |  |  |  |
| **CRA investigator time for initial training of patients on the self-questionnaire – electronic (1 hour/patient) / paper (30 minutes/patient) if > 5 self-questionnaires: electronic (1 hour 30/patient) / paper (45 minutes/patient)** | Per patient | cost | electronic €57,5 paper €28,75 if > 5 self-questionnaires  electronic €86,25 paper €43,12 |  |  |  |
| **CRA investigator time for managing sampling kits.** 1 hour/visit with centralised sampling. *List visits* | Per visit | cost | 57,50 € |  |  |  |
| **CRA investigator time for IVRS/IWRS call** *List visits* | pro rata | cost | 11,24 € |  |  |  |
| **CRA investigator time for managing reimbursements for travel expenses (meals, patient and accompanying person’s hotel, transport)** 20 minutes if the intervention is carried out without the use of a platform 50 minutes if the intervention is carried out using a platform *List visits* | Per visit | cost | without platform: €19,17 with platform: €47,92 |  |  |  |
| **Estimated nursing time – €52/h** | | | | | |  |
| Existing classifications take into account the patient’s routine care The additional nursing time increases the cost of the performance of these procedures within the constraints of the protocol over and above standard practice: => compliance with protocol requirements; => compliance with the requirements of the laboratory manual; => use of specific protocol kits; => completion of protocol forms. Use of AMI pricing. | | | | | |  |
| **Registered nurse (IDE) time**: initial protocol training  - 100 euros level 1 - 200 euros level 2 - 300 euros level 3 | per institution | cost | - 100 euros level 1 - 200 euros level 2 - 300 euros level 3 |  |  |  |
| **Nursing time for taking blood samples for centralised analysis -** 15 minutes *List visits* | Per visit | cost | 13,00 € |  |  |  |
| **Nursing time for taking urine samples for centralised analysis -** 15 minutes *List visits* | Per visit | cost | 13,00 € |  |  |  |
| **Nursing time for measuring vital signs** - 15 minutes *List visits* | Per measuring of vital signs | cost | 13,00 € |  |  |  |
| **Nursing time for study treatment injection** - 15 minutes *List visits* | Per injection | cost | 13,00 € |  |  |  |
| **Nursing time for insertion and removal of drip** - 30 minutes *List visits* | Insertion and removal | cost | 26,00 € |  |  |  |
| **Nursing time for insertion and removal of catheter** - 30 minutes *List visits* | Insertion and removal | cost | 26,00 € |  |  |  |
| **Nursing time for helping the doctor carry out a technical or other procedure** | Per visit | cost |  |  |  |  |
| **Nursing time per PK/PD point** - 15 minutes *List visits* | Per PK/PD point | cost | 13,00 € |  |  |  |
| **Radio manipulator time** administration of the radiation for the treatment under study - 30 minutes List visits | Per administration per patient | cost | 28,75 € |  |  |  |
| **CODED PROCEDURES** | | | | | |  |
| **Procedure** *List visits* |  | additional cost |  |  |  |  |
| **NON-CODED CLINICAL PROCEDURES AND MEDICAL TECHNIQUES** | | | | | |  |
| **Procedure** *List visits* |  |  |  |  |  |  |
| **STAYS AND CONSULTATIONS** | | | | | |  |
| **Additional medical consultation** Specific to research *List visits* | Per consultation | additional cost | tarif CCAM CS ou CNPSY ou CSC |  |  |  |
| **Additional medical consultation,** **medical specialty** List visits | Per consultation | additional cost |  |  |  |  |
| **Rates for hotel stays <24h**  Expenses related to meals, cost of providing a room, heating, fluids, technical services, medical and nursing follow-up time (rate costs differ from those charged for additional procedures related to research carried out during the day) => the rate must correspond to the actual occupation required by the protocol, a bed, a chair: the occupancy is not routine. the rate includes 1 hour of medical time + 1 hour of nursing time + meals.  *List visits* | Rate per visit | additional cost | 429,09 € |  |  |  |
| **Rates for hotel stays >24h** Expenses related to meals, cost of providing a room, heating, fluids, technical services, medical and nursing follow-up time (rate costs differ from those charged for additional procedures related to research carried out during the day) => the rate must correspond to the actual occupation required by the protocol, a bed, a chair: the occupancy is not routine. the rate includes 2 hours of medical time + 2 hours of nursing time + meals.  *List visits* | Rate per visit | additional cost | 808,74 € |  |  |  |
| **OTHER COSTS/ADDITIONAL COSTS ATTRIBUTABLE TO RESEARCH** | | | | | |  |
| **All additional fees that are unexpected, but attributable to the research** |  | cost |  |  |  |  |
| **SAFETY** | | | | | |  |
| Cost of serious adverse event attributable to research - 1 hour of CRA investigator time and 20 minutes of medical time. | Per SAE | cost | 135,57 € |  |  |  |
| Follow-up cost of serious adverse events attributable to research 30 minutes CRA investigator time and 10 minutes medical time | Per SAE follow-up | cost | 76,90 € |  |  |  |
| **Serious and unexpected adverse reactions (SUARs)/‘Line listing**: training/platform set-up 1 hour CRA investigator time 30 minutes medical time (if applicable) | Per trained member of staff | cost | 115,70 € |  |  |  |
| **Management of serious and unexpected adverse reactions /** ‘Line listing’: - paper: flow management, distribution and providing information to the team, archiving or  - platform: flow management, connection to the platform, downloading of SUARs, distribution and providing information to the team, email archiving | Annual cost from signing of contract to closing letter | cost | paper: 100€ platform: 300€ |  |  |  |
| **Additional medical time (€116,4/h)** | | | | | |  |
| **Medical time** Medical time in addition to routine practice: training, specific examination,telephone follow-up, remote consultation not taken into account in procedures carried out as part of research, per hour. *List visits* | Per patient | cost | 116,40 € |  |  |  |
| **Medical time – medical specialty** Medical time over and above standard practice: training, specific examination, telephone follow-up, and not taken into account in the procedures carried out as part of the research involving human subjects (RIPH), per hour *List visits* | Per patient | cost | 116,40 € |  |  |  |
| **Medical time:** participation in teleconferences 1 hour Applicable for phase 1 trials | Per teleconference | cost | 116,40 € |  |  |  |
| **Medical time: Specific training requested by the sponsor or its service provider** 1 hour per training session | per trained member of staff and per training session requested | cost | 116,40 € |  |  |  |
| **Additional CRA investigator time (€57,5/h)** | | | | | |  |
| **CRA investigator time** New consent (following a substantial change) Transmission, recovery, traceability | Per patient and per consent version  15 minutes | cost | 28,75 € |  |  |  |
| **CRA investigator time: Specific training requested by the sponsor or its service provider** 1 hour per training session | per trained member of staff and per training session requested | **cost** | 57,50 € |  |  |  |
| **CRA investigator time: initial training on the transport reimbursement management platform 1 hour** | Cost per institution | cost | 57,50 € |  |  |  |
| **CRA investigator time** **Amendment of study documents (protocol appendix) 30 minutes** (laboratory manual, CRF guideline, etc.) | Per amendment | cost | 28,75 € |  |  |  |
| **CRA investigator time for protocol amendment requiring revision of study documents** + 3 hours | Per amendment | cost | Amendement without modification document: 57,5€ Amendement with modification document: 172,5€ |  |  |  |
| **CRA investigator time for logistical management of the study (1 hour)** List visits | Per examination | cost | 57,50 € |  |  |  |
| **Nursing time: additional cost (€52/h)** | | | | | |  |
| **Registered nurse (IDE) time**: training in the amended protocol | per amendment | cost | 150,00 € |  |  |  |
| **Other costs related to equipment loaned as part of the study** | | | | | |  |
| **Cost of biomedical services where machines or equipment are used**  (If applicable) | per institution | cost | 100,00 € |  |  |  |
| CRA investigator time for management of materials supplied, management of consumables, return packaging –  1 hour 30 minutes | per piece of equipment | cost | 86,25 € |  |  |  |
| **Specific cost of GMO/CAR T-cell study** | | | | | |  |
| **Cost of hygiene, dressing, decontamination, cleaning.** | Per patient per administration | additional cost | 300,00 € |  |  |  |
| **Cost of hospital admission for GMO/CAR T-cell – DRG 6404** | per patient per day in hospital | additional cost | 808,74 € |  |  |  |
| **CRA investigator time: Hygiene kit patient training 1 hour** | per institution | cost | 57,50 € |  |  |  |
| CRA investigator time for GMO studies –  GMO identification of sampling tubes if not carried out by the sponsor or its service provider - 1 hour per visit per patient | Per patient per visit | cost | 57,50 € |  |  |  |
| **Resuscitation** | | | | | |  |
| **Intensive care unit cost:** protocol training – setting up a monitoring system (if applicable) | per institution | cost | 300,00 € |  |  |  |
| **Other** | | | | | |  |
| **Research closure cost Level 1: 30 minutes of medical time + 2 hours of CRA investigator time Level 2: 30 minutes of medical time + 3 hours of CRA investigator time Level 3: 1 hour of medical time + 3 hours of CRA investigator time** | Rate per research programme | cost | level 1: €173.2 level 2: €230.07 level 3: €288.9 |  |  |  |
| **Reagents and consumables:** imposed by the protocol. Excluding routine analyses. Invoice or standard rate/per visit. | Per line | cost | ACTUAL COSTS |  |  |  |
| **LAB TESTING – ANATOMICAL PATHOLOGY** | | | | | |  |
| **Time coordinating lab testing/pathology research** Contribution to: selection, verification of the coordinator matrix: information, introduction of flags, changes to practices, results, etc. 1 hour 30/coordinating or partner centre | Per centre | cost | 86,25 € |  |  |  |
| **Lab testing/pathology research time** Transmission of documents (CV, QC, if cryopreservation: TC (temperature curves), PC (probe calibration), MMC (metrology and maintenance checks). 1 hour 30 (if required by the protocol). | Per centre | cost | 86,25 € |  |  |  |
| **Sponsor audit in the testing or pathology laboratory:** preparation, follow-up, corrective measures. 4 hours/audit (if applicable) | per audit | cost |  |  |  |  |
| **LAB TESTING – Coded Procedure – NABM RIHN** | | | | | |  |
| **Coding:** description of analyses, panel with NABM code and individual or overall pricing. *List visits* | Per work-up | additional cost |  |  |  |  |
| **Safety cost (9105) and Pre-analytical cost (9005) – B22**  *List visits* | 1 time/day/patient | additional cost |  |  |  |  |
| **LAB TESTING – Non-NABM RIHN procedure** | | | | | |  |
| **Lab tech time Management and technical processing of biological samples;** centrifugation, aliquoting, freezing, traceability and preparation of same-day ambient and dry ice shipments (1 hour).  *List visits* | Per visit | cost | 57,50 € |  |  |  |
| **Lab tech time Management and technical processing of PK blood samples.** Preparation and dispatch to the centralised lab chosen by the sponsor 30 minutes/PK point *List visits* | Per PK point | cost | 28,75 € |  |  |  |
| **Lab tech time Specific preparation** (if preparation required in the protocol, to be priced based on the research). *List visits* | per point | cost | 28,75 € |  |  |  |
| **Lab tech time ‘Web entry platform’** Setting up training 2 hours/lab tech  (if applicable) | per member of staff | cost | 115,00 € |  |  |  |
| **Lab tech time Preparation and follow-up monitoring:** 60 min/monitoring pro rata (if applicable) | per monitoring visit | cost | 57,50 € |  |  |  |
| **Lab tech time ‘Amendment to the Lab Manual’ – Drafting/Training:** 2 hours/substantial amendment pro rata (if applicable) | per amendment | cost | 115,00 € |  |  |  |
| **Preservation for research purposes** Storage and release of any type of sample (serum plasma, urine, DNA, etc.) if required by the protocol. To be priced on a pro rata basis based on the number of years. | Annual rate | cost | 224,72 € |  |  |  |
| **Time taken to set up an activity not forming part of the routine system, which is required by research in a specialist laboratory.** Laboratory biologist time: 4 hours Lab tech time: 4 hours | Per specialist laboratory/research programme | cost | 696,80 € |  |  |  |
| **Time to set up a ‘Central Lab’ activity in the lab testing department/CBR** Lab tech time: 9 hours | Per specialist laboratory/research programme | cost | 517,50 € |  |  |  |
| **Time for coordinating implementation by on-call staff: implementation meeting, drafting flag and procedure, training CRA investigator coordinating time: 8 hours Lab tech training time: 6 hours × 2** | Per centre accepting this specificity (at the explicit request of the sponsor) If applicable | cost | 1 150,00 € |  |  |  |
| **ANATOMICAL PATHOLOGY – Coded CCAM procedure** | | | | | |  |
| Procedure | Per procedure | additional cost |  |  |  |  |
| **ANATOMICAL PATHOLOGY – Non-coded CCAM procedure** | | | | | |  |
| **Preparation and dispatch of fresh or archived biopsy** **for centralised second reading** Identification of blocks, preparation of slides (white or coloured), management of dispatch forms (filling in and filing). *List visits* | Per block or biopsy sent | cost | 168,54 € |  |  |  |
| **ACP doctor time: expertise; selection of the block and the area of interest for the biopsy before processing and sending to the central lab.** *List visits* | Per visit 1 hour 30 minutes | Cost | 174,60 € |  |  |  |
| **Lab tech time Specific preparation** (if preparation required in the protocol, to be priced based on the research). *List visits* | per visit | cost |  |  |  |  |
| **Lab tech time for specific preparation: slides if >20** *List visits* | Per batch of 5 slides (over 20) | Cost | 11,24 € |  |  |  |
| **Cost for removal of tumour blocks from the archive of an external laboratory** (€50 or if > €50, on an actual basis on presentation of an invoice). | Per removal | cost |  |  |  |  |
| **IMAGING** | | | | | |  |
| Cost of setting up imaging research 4 hours CRA investigator time + 1 hour medical time | Per centre | cost | 346,40 € |  |  |  |
| **Cost of complex imaging** If the protocol requires specific imaging expertise. Receipt required. | Per centre | cost |  |  |  |  |
| **Review of an examination carried out outside the centre -** 30 minutes medical time. | Per examination | cost | 58,20 € |  |  |  |
| **Cost of specific maintenance** (if not already included). | Per piece of equipment if applicable under the protocol | cost | 112,36 € |  |  |  |
| **Specific expert imaging tasks: data anonymisation/burning, CD burning 30 minutes CRA investigator time List visits** | Per examination | cost | 28,75 € |  |  |  |
| **CRA investigator time: sending images via internet platforms or DVD and transmitting DTFs (data transmittal form) - 30 minutes CRA investigator time  List visits** | Per examination | cost | 28,75 € |  |  |  |
| **Coded procedures** | | | | | |  |
| **Standard examination** = CCAM base + maximum technical fee + modifier + digital archiving fee + drug or diagnostic agent *List visits* | Per examination | additional cost |  |  |  |  |
| **Examination longer than standard or with additional sequences or incidences or with specific post-treatment** = (CCAM base + maximum technical fee + modifier) x additional time/average duration + drug or diagnostic agent *List visits* | Per examination | additional cost |  |  |  |  |
| **Non-coded procedures** | | | | | |  |
| **Examination without CCAM base = actual cost** *List visits* | Per examination | additional cost | frais réel |  |  |  |
| **Additional medical time** **for complex imaging research requiring non-standard patient management -** 1 hour of medical time | Per centre | cost | 116,40 € |  |  |  |
| **Additional CRA investigator time for complex imaging research requiring non-standard patient management - 4 hours of CRA investigator time** | Per centre | cost | 230,00 € |  |  |  |
| **CRA investigator time for monitoring with sponsor/CRO: preparation of patient files, site visits - 2 hours 30 minutes of CRA investigator time per monitoring visit** | Per monitoring visit If applicable | cost | 143,75 € |  |  |  |
| **CRA investigator time for queries - 15 minutes CRA investigator time per examination if applicable** | Per examination | cost | 14,37 € |  |  |  |
| **CRA investigator time for managing samples taken during imaging - 1 hour/sample (if not included in the anatomopathology section). List visits** | Per sample If applicable | cost | 57,50 € |  |  |  |
| **CRA investigator time for CRF entry - 15 minutes/5 completed pages of CRF** | 5 completed CRF pages | cost | 14,37 € |  |  |  |
| **Medical time: post-treatment tasks (reconstructions, measurements, etc.) -** 30 minutes medical time *List visits* | Per examination If applicable | cost | 58,20 € |  |  |  |
| **Medical time for imaging expertise at the sponsor’s request and within the framework of the protocol: know-how, intellectual investment, scale-based intellectual fee and quality indicators = all examinations, including examinations carried out externally -** 1 hour of medical time *List visits* | Per examination If applicable | cost | 116,40 € |  |  |  |
| **PHARMACY – RADIOPHARMACY – MEDICAL DEVICES** | | | | | |  |
| **Cost of pharmaceuticals or radiopharmaceuticals, 1st year, excluding coordination** | Per centre | cost | level 1: 600€  level 2:1200€ level 3:1800€ |  |  |  |
| **Cost of pharmaceutical coordination (coordinating centre)** | Per centre | cost | 400,00 € |  |  |  |
| **Cost of pharmaceuticals or radiopharmaceuticals, additional year** Pro rata for additional years. | Per centre and per year | cost | level 1: 250€  level 2:500€ level 3:750€ |  |  |  |
| **Receipt/delivery** | Per receipt/delivery | cost | 58,20 € |  |  |  |
| **Returnable parcels** | Per return | cost | 29,10 € |  |  |  |
| **Storage – Preservation conditions (excluding cryopreservation)** | per year | cost | 50,00 € |  |  |  |
| **Cryopreservation** | Per year | cost | 300,00 € |  |  |  |
| **Dispensing rate**  *List visits* | Hourly cost per dispensing line | cost | 87,30 € |  |  |  |
| **Sending experimental or ancillary products to the patient’s home or place of residence or to a patient representative** | Per shipment | cost | 232,80 € |  |  |  |
| **Maintenance costs for all appliances/equipment** | per year | cost | 112,36 € |  |  |  |
| **Reconstitution/preparation of medicines/assembly of MD in non-sterile conditions MED and/or MD**  Excluding ATMP and RP: see specific rates | Per procedure | cost | 75,00 € |  |  |  |
| **Reconstitution/preparation of medicines/assembly of MD in sterile conditions MED and/or DM**  Excluding ATMP and RP: see specific rates | Per procedure | cost | 125,00 € |  |  |  |
| **Setting up + decontaminating and/or sterilising a standardised tray (MD)** *List visits* | Per tray | cost | 125,00 € |  |  |  |
| **Cost of blinding carried out by the pharmacy (5 hours)** | Rate per research programme | cost | 600,00 € |  |  |  |
| **Labelling or re-labelling** | programme rate | cost | 116,40 € |  |  |  |
| **Labelling or re-labelling** | In packs of 10 labelled units | cost | 58,20 € |  |  |  |
| **IWRS/RTSM/e-CRF procedures** All procedures are billed if accepted and carried out by the pharmacy | Per procedure | cost | 11,24 € |  |  |  |
| **Destruction** | On an ongoing basis | cost | 9,00 € |  |  |  |
| **Destruction or return of experimental products and/or auxiliaries to the sponsor** | Per programme | cost | 89,89 € |  |  |  |
| **Follow-up monitoring visit** | Per visit | cost | 100,00 € |  |  |  |
| **Audits (including preparation time)** This does not include inspections by the competent authorities. Not applicable to MD. | Per audit | cost | 400,00 € |  |  |  |
| **Research closure cost** | Rate per research programme | cost | level 1: 116,4€  level 2: 174,6€ level 3: 232,8€ |  |  |  |
| **Specific traceability** A single rate of €78.65 for the research as a whole: ATMP, RP, PDMP, IMD and drugs Excluding ATMP: see specific rate | Per centre | cost | 78,65 € |  |  |  |
| **Referencing and entry of a protocol in prescription software** (only on a case-by-case basis with justification in case of complex reconstitution of products for research (e.g. cytotoxics, monoclonal antibodies). | Per centre | cost | 150,00 € |  |  |  |
| **Supply of health product** Purchase of pharmaceutical product: purchase price and pharmacist time (purchase, supply, pharmaceutical management of experimental or non-experimental medicines or medical devices). | Per command line or per complete system for a MD | additional cost |  |  |  |  |
| **Pharmacy – non-coded procedures** | | | | | |  |
| **Initial pharmacist training** in protocol excluding CBP(based on pharmacist time). | Per trained member of staff | cost | 116,40 € |  |  |  |
| Initial HPD training in protocol excluding CBP (based on CRA investigator time) | Per trained member of staff | cost | 57,50 € |  |  |  |
| **Pharmacist training on** protocol **amendments**, if applicable to the pharmacy (based on pharmacist time) | Per trained member of staff | cost | 116,40 € |  |  |  |
| **HPD training on protocol amendments, if applicable to the pharmacy (based on CRA investigator/HPD time)** | Per trained member of staff | cost | 57,50 € |  |  |  |
| **Storage/archiving for in-house pharmacy** (€11.24 per regulatory year). | Per centre | cost | 11,24 € |  |  |  |
| **Pharmacy – Specificities, Advanced therapy medicinal products/GMOs** | | | | | |  |
| **Additional ATMP/GMO rate** | Per centre | cost | 2 000,00 € |  |  |  |
| **Receipt in dry ice or LN2 (e.g. dryshipper)** | Per procedure | cost | 232,80 € |  |  |  |
| **Reconstitution/preparation of ATMP/GMO** | Per procedure | cost | 300,00 € |  |  |  |
| **ATMP/GMO dispensing rate** | Per dispensation | cost | 200,00 € |  |  |  |
| **Specific ATMP/GMO traceability and identity monitoring of autologous products** | Per centre | cost | 210,00 € |  |  |  |
| **Destruction of ATMP/GMO** | Per procedure | cost | 500,00 € |  |  |  |
| **Pharmacy – Specificities, Radiopharmaceuticals** | | | | | |  |
| **Cost of validation and preliminary employee exposure studies** Experimental RP only | per centre | cost | 1 500,00 € |  |  |  |
| **Radiation protection equipment cost** | per dispensation | cost | 5,00 € |  |  |  |
| **Additional experimental or auxiliary RP package** **If radiosynthesis protocol to be implemented on automated system** | Per centre | cost | 2 000,00 € |  |  |  |
| **UN2910 package return** RPH 30 minutes | per return |  | 58,20 € |  |  |  |
| **Complex preparation with experimental or auxiliary RP automated system** If automated system required | Per procedure | cost | 349,20 € |  |  |  |
| **Quality control of experimental or auxiliary RP** | Per procedure | cost | 58,2€ or actual cost if >30min |  |  |  |
| **Regulation-compliant storage of radioactive waste before destruction** Depending on the physical half-life of the radionuclide | Per dispensed product and per day of storage (storage time = 10 periods of the radionuclide with the longest half-life) | cost | 11,24 € |  |  |  |
| **Time taken to set up an activity not forming part of the routine system, which is required by research in a specialist laboratory.** Pharmacist time: 4 hours + HPD time: 4 hours | Per department involved in radiopharmacy | cost | 761,60 € |  |  |  |
| **HPD time. Management and technical processing of blood samples.** Preparation and dispatch to the centralised lab chosen by the sponsor Regulation-compliant storage of radioactive waste before destruction *List visits* | Per PK point 30 minutes | cost | 37,00 € |  |  |  |
| **Labelling of radiopharmacy tubes** | rate per quarter | cost | 172,50 € |  |  |  |
| **Cost of preservation for research purposes for PK analysis** Storage and release of any type of sample (serum plasma, urine, DNA, etc.) if required by the protocol | Annual rate | cost | 224,72 € |  |  |  |
| **RPH interpretation time** (30 minutes) following multiple measurement of controls | per visit | cost | 58,20 € |  |  |  |
| **TOTAL** |  |  |  |  |  |  |

### Annexe 2.2

|  |  |  |
| --- | --- | --- |
| Invoicing procedures within each of the Parties | | |
|  |  |

All amounts are given exclusive of tax.

The amounts invoiced will be increased by the value added tax (VAT) at the rate in force at the time of invoicing (if applicable).

*[If necessary, to be completed by the Establishment and the Company and where appropriate* third-party structure*. See the example below:*

*Receipts must be made out to (choose the appropriate item): [o be duplicated for parties] :*

* *If no company commissioned:*

*Name of the sponsor / Department / Office / Address(es)*

* *If company commissioned:*

*XXX - In the name of and on behalf of XXX,/ Address(es)*

*and sent by post to:*

*XXX, / To the attention (first name, last name) of / Address(es)*

*Or by e-mail at:*

*E-mail address for sending invoices*]

Payment for Appendix 2 must be made to the order of:

[Insert the beneficiary's bank details]

An invoice will be issued (specify frequency)

The reference to appear on the receipt or invoice is: XXXX

### Appendix 3

|  |
| --- |
| Processing clause according to article 28 of the General Data Protection Regulation |

**I. Objective**

The purpose of these clauses is to define the conditions under which the processor undertakes to carry out the personal data processing operations defined below on behalf of the controller.

In the context of their contractual relations, the Parties undertake to comply with the regulations in force applicable to the processing of personal data and, in particular, the General Data Protection Regulation and the Act No. 78-17 of 6 January 1978 on Information Technology, Data Files and Civil Liberties, as amended.

**II. Description of the processing to be carried out by the processor on behalf of the controller**

The processor is authorised to process on behalf of the controller the personal data that are necessary in order to provide for the tasks described in this agreement.

The nature of the operations performed on the data is defined in the Protocol.

The purpose of the processing is to carry out the Research. The personal data processed are those defined in the Protocol and in the case report forms used in the Research, whether on paper, or in electronic form or in any other media. The categories of data subjects are those who are, or wish to be, involved in the Research.

The nature of the operations carried out and in particular the processing of personal data carried out, where applicable, by the Third-party Structure(s), in the context of the Protocol, are specified in the table below:

|  |  |
| --- | --- |
| **Designation of the  Third-party Structure(s)** | **Nature of the operations carried out /  Personal data processing performed** |
|  |  |
|  |  |
|  |  |

For the performance of the task subject to this agreement, the controller shall provide to the processor the following information, to the extent it is available:

* the Research Protocol;
* the case report forms;
* information notes and/or consent forms;
* the opinions and authorisations of the competent authorities and, where applicable, the receipt for the declaration of conformity of the Research with the applicable reference methodology.

The controller shall provide to the processor the latest versions of the documents relating to the Research.

**III. Term**

The effective date and term of these clauses are defined in Article 10 of this agreement.

**IV. Obligations of the processor with regards to the controller**

The processor undertakes to:

1. process the data solely for the purpose(s) subject to the sub-contracting;
2. process the data in accordance with the controller's documented instructions mentioned in the Protocol and the case report forms relating to the Research. If the processor considers that an instruction infringes the General Data Protection Regulation or any other Union or Member State data protection provisions, it shall immediately inform the controller of this. In addition, if the processor is required to transfer data to a third country or to an international organisation under European Union law or the law of the Member State to which it is subject, it must inform the controller of this legal requirement before processing, unless that law prohibits such information on important grounds of public interest;
3. guarantee the confidentiality of the personal data processed in the framework of this agreement;
4. ensure that the persons authorised to process the personal data on the basis of this agreement:

* have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;
* receive the necessary training on the protection of personal data;

1. ensure that the persons responsible for quality control and quality assurance, mandated and authorised by the controller, have access only to the individual data necessary for such control.
2. Use of sub-processors

The processor is allowed to engage the entity ....................................................... (hereinafter, the "sub-processor") to carry out the following processing activities: ………………………………………………………..

In the event of the engagement of other sub-processors, the processor must obtain the prior specific written authorisation of the controller.

The data protection obligations set out in this agreement and this appendix shall be imposed by the processor on sub-processors by means of a written agreement. It is the responsibility of the initial processor to ensure that the sub-processor presents the same sufficient guarantees as regards the implementation of appropriate technical and organisational measures in such a manner that the processing will meet the requirements of the General Data Protection Regulation. Where the sub-processor fails to fulfil its data protection obligations, the initial processor shall remain fully liable to the controller for the performance of the sub-processor's obligations.

1. Data subjects’ right to information

The processor, at the time of collection of the data, must provide the individuals involved in the Research with information on the data processing it carries out. The wording and format of the information is developed by the controller and approved by the Committee for Protection of Persons (*Comité de Protection des Personnes*) prior to the collection of data.

1. Exercise of data subjects’ rights

The data subjects shall exercise their rights with the processor.

The processor shall inform the controller, as soon as possible and within a maximum period of 72 hours, of any data subject’s request it receives. When the controller has appointed a Data Protection Officer (DPO), the processor shall inform the controller’s DPO of the data subject’s request. The processor shall communicate to the controller, or where applicable to the controller’s DPO, only the data allowing to handle the data subject’s request, including the individual’s inclusion number, without revealing the data subject’s full identity and/or contact details.

The controller shall instruct the processor on how to handle the request and shall provide the processor with the content of the answer to be given.

The processor shall confirm to the controller that the request has been handled according to its instructions.

1. Notification of personal data breaches

The processor shall notify the controller of any breach of personal as defined in Article 4.12 of the General Data Protection Regulation within 48 hours of becoming aware of it. This notification shall be accompanied by all relevant documentation to enable the controller, if necessary, to notify the breach to the competent supervisory authority.

The notification shall include at least:

* a description of the nature of the personal data breach including, where possible, the categories and approximate number of data subjects concerned by the breach and the categories and approximate number of personal data records concerned;
* the time elements (day and time) of the occurrence and of becoming aware of the personal data breach;
* the name and contact details of the processor’s data protection officer or another contact point where additional information can be obtained;
* a description of the likely consequences of the personal data breach;
* a description of the measures planned/proposed by the processor to address the personal data breach, including, where appropriate, measures to mitigate its possible adverse effects.

Where, and in so far as, it is not possible to provide the information at the same time, the information may be provided in phases without undue further delay.

Upon the controller’s approval , the processor shall, in the name and on behalf of the controller, communicate the personal data breach to the data subject(s) without undue delay, , when the personal data breach is likely to result in a high risk to the rights and freedoms of a natural person.

The communication to the data subject(s) shall describe in clear and plain language the nature of the personal data breach and includes at least:

* a description of the nature of the personal data breach including, where possible, the categories and approximate number of data subjects concerned by the breach and the categories and approximate number of personal data records concerned;
* the time elements (day and time) of the occurrence and of becoming aware of the personal data breach;
* the name and contact details of the processor’s data protection officer or another contact point where additional information can be obtained;
* a description of the likely consequences of the personal data breach;
* a description of the measures planned/proposed by the processor to address the personal data breach, including, where appropriate, measures to mitigate its possible adverse effects.

1. Assistance provided by the processor with regards to the controller’s obligations

The processor shall assist the controller in carrying out data protection impact assessments (data subjects’ rights, security of processing, breach notification, etc.), according to the processor’s capabilities.

The processor shall assist the controller in carrying out the prior consultation of the supervisory authority, if necessary.

1. Security measures

The processor undertakes to implement technical and organisational measures that ensure a level of security appropriate to the risk presented by the processing and to keep at the disposal of the controller any documentation allowing it to keep the controller informed of this if necessary.

In particular, in the specific context of this agreement, the processor must either adopt the following measures or demonstrate equivalent measures or the fact that it does not have a need to use such measures:

| **Categories** | **Measures** |
| --- | --- |
| Raising user awareness | Informing and raising awareness of the persons manipulating the data |
| Preparing an IT charter and giving it binding force |
| Authenticating the users | Defining a unique identifier (login) for each user |
| Adopting a user password policy in accordance with the recommendations of the CNIL |
| Obliging the user to change his/her password after reinitialisation |
| Limiting the number of attempts to access an account |
| Managing the authorisations | Defining the authorisation profiles |
| Deleting the obsolete access permissions |
| Carrying out an annual review of authorisations |
| Tracing the access and managing incidents | Providing for a logging system |
| Informing the users that a logging system has been put in place |
| Protecting the logging equipment and the logged information |
| Providing for procedures for reporting violations of personal data |
| Securing the work stations | Providing for an automatic procedure to lock the session |
| Using regularly updated anti-virus software |
| Installing a software firewall |
| Collecting the consent of the user before any intervention on his/her equipment |
| Securing the mobile information equipment | Providing for means of encryption for mobile equipment |
| Making regular backups or synchronisations of the data |
| Requiring a secret for unlocking smart phones |
| Protecting the internal information network | Limiting the network flows to what is strictly necessary |
| Securing remote access to mobile information devices by VPN |
| Implementing WPA2 or WPA2-PSK protocol for Wi-Fi networks |
| Securing the servers | Limiting access to the administrative tools and interfaces solely to authorised persons |
| Installing critical updates without delay |
| Ensuring the availability of the data |
| Securing the web sites | Using the TLS protocol and verifying its implementation |
| Verifying that no password or identifier passes through the URLs |
| Controlling that the entries by users correspond with what is expected |
| Installing a banner for consent to tracers (cookies) that are not necessary for the service |
| Protecting and providing for the continuity of the activity | Making regular backups |
| Storing the backup media in a safe location |
| Providing for secure means for conveying backups |
| Providing and regularly testing the continuity of the activity |
| Archiving in a secure manner | Implementing specific terms of access for the archived data |
| Destroying obsolete archives in a secure manner |
| Managing the maintenance and destruction of data | Logging the maintenance interventions in a log book |
| Managing interventions by third parties by means of a responsible person from the organisation |
| Deleting the data from any equipment before scrapping it |
| Managing the sub-contracting | Providing for a specific clause in the agreements with processors |
| Providing for conditions for the restitution and destruction of the data |
| Ensuring the effectiveness of the guarantees provided (security audits, visits, etc.) |
| Securing the exchanges with other organisations | Encrypting data before sending it |
| Ensuring that this is the correct recipient |
| Transmitting the secret by a separate message and via a different channel |
| Protecting the premises | Restricting access to the premises with locked doors |
| Installing anti-intrusion alarms and verifying them periodically |
| Managing the software developments | Proposing parameters that ensure the privacy of the final users |
| Avoiding comments zones or managing them strictly |
| Testing on fictional or anonymised data |
| Using cryptographic functions | Using recognised algorithms, software and libraries |
| Retaining the secrets and the cryptographic keys in a secure manner |

The processor also undertakes to implement the security measures provided for in the Protocol, the Good Clinical Practice and, where applicable, the applicable reference methodology.

1. Fate of data

Under this agreement, the processor shall keep the data in in an active data base and in an intermediary archive for the periods specified in the Protocol.

At the end of the services provided in connection with the processing of such data (including, where applicable, the intermediate archiving of the data), the processor undertakes to:

* option A: delete all the personal data or;
* option B: return all the personal data to the controller or;
* option C: return the personal data to the CRO or to the processor appointed by the controller for this purpose.

The Parties agree to implement option ................................................... in the context of this agreement.

The return must be accompanied by the deletion of all existing copies in the processor's information systems, unless there is a legal obligation to archive. Once deleted, the processor must document the deletion in writing.

1. Data Protection Officer

The contact details of the DPO, if any, appointed by each of the Parties, in accordance with Article 37 of the General Data Protection Regulation, are set out in appendix I.

Each Party shall inform the other Party of any change in the contact details of the appointed Data Protection Officer.

1. Record of categories of processing activities

The processor represents and warrants that it keeps a written record of all categories of processing activities carried out on behalf of the controller including:

* the name and contact details of the controller on behalf of which it is acting, any processors and the Data Protection Officer, if any;
* the categories of processing carried out on behalf of the controller;
* where applicable, transfers of personal data to a third country or an international organisation, including the identification of that third country or international organisation and, in the case of transfers referred to in the second subparagraph of Article 49(1) of the General Data Protection Regulation, the documentation of suitable safeguards;
* where possible, a general description of the technical and organisational security measures, including, among others, as necessary:
  + the pseudonymisation and encryption of personal data;
  + the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services;
  + the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident;
  + a process for regularly testing, assessing and evaluating the effectiveness of the technical and organisational measures for ensuring the security of the processing.

1. Documentation

The processor shall make available to the controller the documentation necessary to demonstrate compliance with all its obligations and to allow audits to be carried out as provided for in Article 9.5 of this agreement, including inspections, by the controller or another auditor appointed by it, and to contribute to such audits.

**V. Obligations of the controller with regards to the processor**

The controller undertakes to:

1. provide the processor with the information referred to in II of these clauses;
2. document in writing any instructions regarding the processing of data by the processor;
3. ensure, beforehand and throughout the duration of processing, that the processor complies with the obligations established by the General Data Protection Regulation;
4. supervise the processing, including carrying out audits and inspections of the processor.

|  |  |  |
| --- | --- | --- |
| **Annexe 4 [optionnelle]** | |  |
| Definition of the CounterpartsFor conducting of the research  specific optional appendix for each health establishment, care home or health centre participating in the research [and/or third-party structure if applicable] | | |
|  |  |  | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Sponsoring company** |  | |  | |
| **CRO company** |  | |  | |
| **Research (Acronym or sponsor reference)** |  | |  | |
| **Health Establishment** |  | |  | |
| **Investigator + study number** | Prof. /Dr. | |  | |
| **Internal structure concerned (Centre, department, etc.)** |  | |  | |
|  |  | | |  | |
|  |  | | |  | |
| **Recipient of consideration** (sole recipient per signatory establishment) |  | | | |  | |
|  |  | | |  | |
| **Allocation of consideration per establishment or third-party structure *(optional)*** | [third-party account, UF/UG - operational and administrative units, third-party structure, etc.] | | | |
|  |  | | |  | |
|  |  | | |  | |
| **Description** | **Comments/observations** | **Amount of consideration** | | |
|  |  |  | | |
|  |  |  | | |
|  |  |  | | |
|  |  |  | | |
|  |  |  | | |
|  |  |  | | |
|  | **Total** |  | | |

**Invoicing procedures within** health establishment, care home or health centre participating in the research [and/or third-party structure if applicable]**:**

All amounts are given exclusive of tax.

The amounts invoiced will be increased by the value added tax (VAT) at the rate in force at the time of invoicing (if applicable).

[If necessary, to be completed]

Payment for Appendix 4 must be made to the order of:

[Insert the beneficiary's bank details]

**Appendix 5 [optional]**

|  |  |  |
| --- | --- | --- |
| Clauses on the provision of materials or equipment | | |
|  |  |

**ARTICLE 1 – SUBJECT**

**1.1.**  This Appendix covers the provision of the following equipment by the Company to the Coordinating Institution:

* Name:
* Manufacturer:
* Type:
* Serial number (if known):
* Delivery date:
* Book value:
* MD or IVDMD: Yes No

hereinafter referred to as ‘**the Equipment**’.

The above-mentioned Equipment is CE marked and/or complies with the standards and regulations in force.

Any costs arising from the commissioning, maintenance and removal of the Equipment, as well as staff training or any other costs arising from the provision of the Equipment, shall be borne by the Company [or the CRO].

The Equipment is provided in the context of the Research referred to in the Single Agreement.

* 1. The contact at the Company [or CRO] for any information concerning the Equipment is:

Name:

Title:

Telephone number:

Email:

**ARTICLE 2 – SERVICE CONCERNED**

The Equipment is made available in the following department(s)/division(s)

of the coordinating institution: *list them*.

**ARTICLE 3 – DELIVERY AND INSTALLATION**

* 1. The installation of the Equipment shall be scheduled after agreement with the department(s)/division(s) concerned and with the biomedical and, if necessary, IT department of the Coordinating Institution so that it can be recorded as an asset of the Coordinating Institution (physical and accounting management of the Equipment). It can only take place after the single agreement or an amendment incorporating this appendix has been signed.
  2. The Equipment shall be delivered and installed in the department(s)/division(s) concerned by the Company [or the CRO] in compliance with the Internal Regulations and internal procedures for the delivery, receipt and commissioning of the Coordinating Institution’s equipment, at the full expense of the Company [or the CRO]. Any damage caused during the delivery, installation and commissioning of the Equipment or during maintenance work must be repaired at the expense of the Company [or the CRO] unless such damage is the result of negligence on the part of the Coordinating Institution; and only if the Coordinating Institution carries out the installation and commissioning, and subject to proof of negligence being established by the Company [or the CRO]. The Coordinating Institution cannot be held responsible for any damage caused during delivery, as delivery is the sole responsibility of the Company [or CRO]. Proof of negligence remains the responsibility of the Company [or the CRO].
  3. At the time of installation, the Company [or the CRO] undertakes to provide the following documents:
* proof of compliance with applicable regulations
* the documentation required for the correct use and operation of the delivered Equipment and for its routine maintenance, as well as instructions for use for each piece of equipment (any corrections will be supplied at no extra cost).

These documents must be written in a language that the head of the department(s) concerned can understand. If this is not the case, the Company [or the CRO] will be responsible for translating these documents into French.

* 1. The Company [or the CRO] shall affix to each piece of Equipment a plate indicating its reference number and its company name, thus enabling its ownership to be identified.
  2. An Equipment acceptance/installation form must be completed and signed by the department(s) concerned and the Company [or the CRO].

**ARTICLE 4 – USE OF THE EQUIPMENT**

4.1. The use of the Equipment made available is reserved, for collective use, solely for the practitioners of the Coordinating Institution who are involved in the Research or the paramedical, medico-technical and other staff working under their authority in this context.

4.2. The Company [or the CRO] shall (if necessary, at the time of commissioning) provide the department(s) concerned with training on the technical characteristics of the Equipment, how it works, the ways in which it can be adjusted and how to maintain it for the personnel who will be using the Equipment. If no training is deemed necessary by the Company [or the CRO], the Coordinating Institution may not be held liable for any improper use of the Equipment.

4.3. Any modification to the Equipment or the protocol for its use, any connection to other equipment not provided for by the Company [or the CRO] or any use of a new type of consumable requires the prior written agreement of the Company [or the CRO].

**ARTICLE 5 – SUPPLIES OF REAGENTS AND CONSUMABLES**

**5.1.** Any consumables and reagents required to use the Equipment made available that is made available shall be provided free of charge by the Company [or the CRO] for the duration of the Research. Consumables will be delivered in accordance with the Coordinating Institution’s internal delivery and acceptance procedures.

**5.2.** In the event of a supply shortage or expiry of the reagents and consumables required for the use of the Equipment, the Coordinating Institution undertakes to inform the Company [or the CRO] immediately in order to enable it to make a new delivery within a reasonable period of time.

**ARTICLE 6 – EQUIPMENT MAINTENANCE**

**6.1.** For the entire duration of the loan, the Company [or the CRO] shall be entirely responsible for preventive and corrective maintenance services, unless the corrective maintenance services are necessary due to negligence on the part of the Coordinating Insitution, which must be proven by the Company. These services shall be carried out in such a way as to ensure that the Equipment functions properly. The Company shall ensure that preventive and corrective maintenance services can be traced. Supporting documents shall be provided to the Coordinating Institution.

**6.2.** Users shall notify the Company [or the CRO] of the need for a repair service by any means. The contacts for the Company [or CRO] are: ***complete name, position, telephone number, email***.The Company [or the CRO] undertakes to carry out the services as soon as possible after receiving notification from the users. If the supplier has a hotline, the telephone numbers and opening hours are as follows: *to be completed*

**6.3.** The biomedical department of the Coordinating Institution will not interfere with the Equipment. However, the Company [or the CRO] undertakes to inform the biomedical department of the Coordinating Institution of any maintenance operation or technical modification. The Company [or the CRO] undertakes to maintain the designated Equipment or have it maintained on its behalf and to:

- replace any mechanical part or electronic component deemed defective by the technician, free of charge. Replaced spare parts shall remain the property of the Company [or the CRO].

- carry out any technical modifications deemed necessary during a maintenance operation. In accordance with applicable requirements, maintenance services will be carried out in accordance with the manufacturer’s recommendations. The Company [or the CRO] shall provide all-risk maintenance for the Equipment provided.

**ARTICLE 7 – INSURANCE AND WARRANTIES**

**7.1.**  In connection with the Research, the Sponsor has taken out insurance with:

- Sponsor’s insurance company: ***to be completed***

- Address: ***to be completed***

- Telephone number: ***to be completed***

**7.2.** The Company [or the CRO] shall bear the financial burden resulting from the loss or theft of the Equipment unless the loss or theft is due to the fault of the Coordinating Institution.

**7.3.** The Parties agree that the warranty for defective products is applicable by virtue of Articles 1245 et seq. of the French Civil Code, without prejudice to the provisions of the Single Agreement concerning the Sponsor’s conclusion of an insurance policy for the Research and its legal obligations.

**7.4.** The Company [or the CRO] warrants that it has taken out insurance for the Equipment with a reputable and solvent company and explicitly and necessarily releases the Coordinating Institution from all liability in the event of any loss or accident suffered or caused by the Equipment, unless it is linked to inappropriate use of the Equipment or failure to comply with the terms and conditions explicitly set out in the instructions for use and in compliance with the provisions of Article 4.2.

**7.5.** The Coordinating Institution releases the Company [or the CRO] from liability for risks of all kinds incurred in the premises (including the risk of fire or water damage) used for conducting the Research, resulting from its activities or resulting from its personnel and declares that it has taken out insurance covering the deterioration of the Equipment made available by the Company [or the CRO] as a result of the aforementioned risks.

The Institution cannot be held liable for damage caused by normal wear and tear of the Equipment.

**7.6** If equipment is loaned to the patient, the patient cannot be held responsible for any loss or theft of the equipment, or for any damage caused to the equipment. The Company will replace or repair the equipment loaned to the patient.

The Institution cannot be held responsible if the patient fails to return the Equipment.

**ARTICLE 8 – FINANCIAL COMPENSATION**

The Equipment is made available without any commitment to purchase it.

No financial compensation will be requested from the Coordinating Institution for the provision of the Equipment.

**ARTICLE 9 – RIGHT OF OWNERSHIP**

The Equipment is and shall remain the property of the Company [or the CRO]. The Company [or the CRO] shall be responsible, at its own expense, for recovering the Equipment at the end of the loan period. The terms of return are defined by agreement between the Parties. In the event that the Company [or the CRO] does not recover the Equipment as agreed at the end of the period of provision and after formal notice, the Coordinating Institution shall remove the Equipment and invoice the Company [or the CRO] for the related costs.

**ARTICLE 10 – PERIOD OF AVAILABILITY**

* 1. The period of availability shall extend from the date of delivery until the date of completion of the Research or until the date of recovery of the Equipment defined by the Company [or the CRO], whichever occurs first.
  2. Scheduled commissioning date of the Equipment: ***to be completed***

**Appendix 6 [optional]**

|  |  |  |
| --- | --- | --- |
| Clauses on the provision of biological resources | | |
|  |  |

**ARTICLE 1 – SUBJECT**

* 1. The purpose of this appendix is for the Coordinating Institution to make available to the Company [or CRO] the biological resources derived from products and elements of the human body described in the research protocol and/or in the laboratory manual,

hereinafter referred to as the ‘**Biological Resources**’.

**ARTICLE 2 – OBLIGATIONS OF THE INSTITUTION**

* 1. The Coordinating Institution undertakes to supply the Biological Resources to the Company [or CRO] in accordance with the transfer procedures set out in the research protocol and/or the laboratory manual.
  2. The Coordinating Institution guarantees that the Biological Resources supplied to the Company [or CRO] are collected in accordance with the legislation and regulations in force.
  3. The Coordinating Institution guarantees that the Biological Resources supplied are not accompanied by any identifying data.
  4. The Coordinating Institution shall not be held liable for any damage or loss resulting from the transport of the Biological Resources.

**ARTICLE 3 – OBLIGATIONS OF THE COMPANY**

* 1. The Company [or the CRO] undertakes to use the Biological Resources only for the purposes of carrying out the Research and in accordance with the information and/or consent forms as validated by the competent authorities that authorised the Research.
  2. The Company [or the CRO] undertakes to bear all the costs associated with all the operations inherent in the transfer of the Biological Resources and to appoint a carrier who meets the conditions described in the research protocol.
  3. The Company [or the CRO] guarantees that it will use the Biological Resources in accordance with the law and in particular with the French regulations relating to the use of human biological samples and associated data and that it will complete all the regulatory formalities necessary for said use (application of a CNIL RM or requirement) and make a declaration to the Ministry of Higher Education and Research regarding the activities involving the preparation and storage of human biological samples.
  4. The Company is not authorised to transfer, donate or assign the Biological Resources to any third party or parties other than those carrying out the analyses and referred to in the research protocol.

**ARTICLE 4 – INSURANCE AND WARRANTIES**

1. The Company shall accept the Biological Resources as they are and recognise that they must be used with prudence and caution.
2. The Coordinating Institution and its staff assume no responsibility for the use of the Biological Resources by the Company.

**ARTICLE 5 – PERIOD OF AVAILABILITY**

The Biological Resources will be made available from ***specify date*** and for the entire duration of the Research.