# 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**

**Clinical Trial No.**

**EudraCt no.…….. or Idrcb no.………**

***Associated 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 “**Associated Establishment**“;

**OR**

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 "**Associated 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**“;

**AND/OR**

**The company** ………………. whose registered office is at ……………… represented by its ……… (position of legal representative), Mr. ………………… (name of legal representative), fully or partially empowered to [sign and/or execute] this agreement in the name and on behalf of the Company and hereafter referred to as “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 Associated Establishment, the Company or the CRO and, where appropriate, the Third-party structure, are hereafter referred to individually as the “Party” or collectively as the “Parties“.

**Having considered:**

The (EU) European 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 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);

The French Public Health Code, particularly its articles L. 1121-16-1 and R. 1121-3-1;

The French Civil Code, particularly its articles 1367 and 1112-2;

The French Defence Code, particularly its articles R. 3232-11 to R. 3232-14;

The Act No. 78-17 of 6 January 1978 on Information Technology, Data Files and Civil Liberties;

The codes of ethics of the health professions;

Decree No. 2008-967 of 16 September 2008 setting out the rules of professional conduct for armed forces practitioners;

The decision 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 Associated 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 Jardé Act]:

* [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 Associated 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 Associated 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]:

* [if the authorisation is in 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 Associated 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 Associated Establishment.

The Associated 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 Associated 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 Associated 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 associated 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 appointed as such by the promoter in accordance with article L. 1121-1 of the French Public Health Code.

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 ASSOCIATED ESTABLISHMENT

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

The Associated 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 Associated 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 Associated 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 Associated 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 Associated 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.

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.

* It provides the management of the Associated Establishment with the following documents and information: Protocol (in French or English), summary of the Protocol in French, [copy of the delegation of powers for monitoring by a CRO], name and title of the signatory of the agreement, addressee and address for the despatch of invoices.
* It provides the Associated Establishment with the proposed list of the Costs, Additional costs and Consideration.
* It informs the Associated 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 4, 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 Associated 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).

The Company, together with the investigator, shall inform the Associated 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 Associated 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 Associated Establishment, already included under the Costs and Additional costs.

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

### 9.1 Confidentiality

The Associated 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 Associated 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 Associated Establishment or investigator and/or Third-party Structure or by any person working in connection with the Research;
* was not communicated to the Associated 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 Associated 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 Associated 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 Associated 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 Associated 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 Associated 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 Associated 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 Associated 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 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 Associated 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 Associated 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 *force 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 Principal 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 Principal 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 Principal 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 Associated 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 Principal Investigator

The personal data relating to the Principal 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 Principal 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 Principal 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 Principal 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 Principal 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 Associated 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 Associated 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 Associated 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] – agreement for provision of equipment and/or biological samples.

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

In X original counterparts.

Per pro/ the Associated Establishment Per pro / the Company

[where appropriate]

Rank Name

First name

Chief Medical Officer of the HIA

|  |  |  |
| --- | --- | --- |
|  |  |  |

Per pro/ the legal representative of the Third-party Structure,

*(where appropriate)*

|  |
| --- |
|  |

Stamp of the Principal 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"*

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| Appendix 1 |
| List and details of contacts in company and establishment |
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| [Contacts concerning the processing of personal data:   * Contact details for the Data Protection Officer (DPO): * Contact for the exercise of rights, if not the DPO: * Contact for further data processing, if not the DPO: * Contact for data breaches, if not the DPO:] |
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| --- | --- | --- | --- | --- | --- | --- |
| 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 | | | |

### Appendix 2.1

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Matrix for calculating costs and additional costs incurred for realisation of research for commercial purposes | | | | | | |
|  |  |  |  |  |  |  |
| **Sponsoring company** |  | | | | | |
| **CRO (where appropriate)** |  | | | | | |
| **EudraCt or Idrcb research no.** |  | | | | | |
| **Name of coordinating or associated establishment** |  | | | | | |
| **FINESS (Ntnl Health/Business File) No.** |  | | | | | |
| **Investigator** |  | | | | | |
| **Centre / Unit** |  | | | | | |
|  |  |  |  |  |  |  |
| **Provisional number of patients for the centre:** |  |  |  |  |  |  |
| **Research complexity level (see appendix 2):** |  |  |  |  |  |  |
| **Table version 01/03/2022 based on the protocol: version 00 of DD/MM/YYYY** | | | |  |  |  |
|  |  |  |  |  |  |  |
| **Evaluation made on the basis of:** | | | | | | |
| **Description of acts performed and services provided:** | **Limit of occurrence** | **Costs or additional costs** | **Unit amount  € (excluding taxes)** | **Number of items per patient or for the centre** | **Total cost for a patient or the centre  € (exc. taxes)** | **Total for the number of patients from the centre or for the centre € (exc. taxes)** |
| **FIXED COSTS** | | | | | | |
| **Fixed administrative costs** | | | | | | |
| **Administrative costs** Registration of the research, procedure for drawing up the agreement and the matrix, financial and administrative monitoring of the agreement, including amendments.  Fixed costs applied per investigation centre and not per establishment, if several investigation centres in the establishment, several fixed costs are charged. Invoiced as from signature of agreement, even if the decision to cancel before starting is attributable to the sponsor (if the matrix has already been prepared). | Per establishment | cost | 500€ for the coordinating centre  200€ for the other associated centres | 1 |  | € 0.00 |
| **Additional costs for drafting endorsement** ONLY if the substantial modification of the matrix is associated with a radical modification of the protocol. | Per establishment | cost | € 100 coordinating centre  € 50 associated centre |  |  | € 0.00 |
| **Implementation of research** Preselection of centre, consideration of protocol and its requirements, feasibility studies, contribution to preparation of matrix, responses to questionnaires to verify exercise of clinical good practice, implementation meeting. Fixed costs invoiced even if no patient included, invoiced as from signature of agreement. | Per establishment | cost | level 1 or extension: € 300 level 2: € 450 level 3: € 600 | 1 |  | € 0.00 |
| **Fixed costs for logistics** | | | | | |  |
| **Fixed costs for logistical costs**Telephone, secretariat for arranging meetings, office equipment, small items, archiving costs for study documents and maintenance of access to data. Participation in hospital operating costs (premises, waste management, sterilisation, etc.), participation in amortisation of hospital investments, etc. (fixed costs applicable to all patients included pro rata to screening and actual inclusion, however many examinations done, including if examinations and additional acts are done throughout the study.*List the visits* | Fixed costs per patient and examination | cost | level 1: € 2 level 2: € 3level 3: € 4Add €1/patient/visit if external personnel are involved (except sponsor, CRO, ARC monitoring) |  |  | € 0.00 |
| **Fixed costs for the maintenance of the equipment** To be evaluated in proportion to the number of years | Per year's study | cost | € 100.00 |  | € 0.00 | € 0.00 |
| **MATTERS FOR INVESTIGATION** | | | | | | |
| **Estimation of medical time - €102/h** | | | | | | |
| **Consultation for Inclusion** doctor informing patient and obtaining consent Research level 1: 1 hr Research level 2: 1 hr 30 Research level 3: 2 hr *List the visit* | Per patient | cost | level 1: € 102  level 2: € 153  level 3: € 204 | 1 |  | € 0.00 |
| **Follow-up by telephone** 15 mn for any type of research.*List the visits* | Per patient | cost | € 25.50 |  | € 0.00 | € 0.00 |
| **Medical time** Medical time exceeding current practice (training, specific examination, telephone monitoring and not included for acts done in relation to the research. Per hour, pro rata. *List the visits* | Per patient | cost | € 102.00 |  | € 0.00 | € 0.00 |
| **Sponsor audit except pharmacy (if < 1 day)**  From preparation to implementation of corrective action (except pharmacy. Specific fees for research on DM). | Per centre | cost | € 300.00 |  | € 0.00 | If applicable |
| **Sponsor audit except pharmacy (if > 1 day)**  From preparation to implementation of corrective action (except pharmacy. Specific fees for research on DM). | Per centre | cost | € 450.00 |  | € 0.00 | If applicable |
| **Estimated Clinical research technician training time (TEC) - € 50.4/h** | | | | | | |
| **Clinical research technician training time** **Research level 1:** 4 or 5 hrs (1 hr for paper CRF, 2 hrs for eCRF, 1 hr for reading protocol, 1 hr for drafting procedure for the service, 1 hr for administrative management). **Research level 2:** 5 or 6 hrs (1 hr for paper CRF, 2 hrs for eCRF, 2 hrs for reading protocol, 1 hr for drafting procedure for the service, 1 hr for administrative management). **Research level 3:** 7 or 8 hrs (1 hr for paper CRF, 2 hrs for eCRF, 3 hrs for reading protocol, 2 hrs for drafting procedure for the service, 1 hr for administrative management) | Per trained personnel | cost | level 1: € 201.6 or € 252  level 2: € 252 or € 302.4 level 3: € 352.8 or € 403.2 | 1 |  | € 0.00 |
| **TEC monitoring time with sponsor/CRO** Per day and per ARC monitor. Preparation of patient files, availability, answering queries (on average and not per number of patient files). **Research level 1:** 2.5 hrs per follow-up examination. **Research level 2:** 4 hrs per follow-up examination. **Research level 3:** 5 hrs per follow-up examination. | Per day and per ARC monitor | cost | level 1: € 126 level 2: € 201.6  level 3: € 252 | 1 |  | Pro rata |
| **TEC remote monitoring time telephone consultation audio-conf) - 2hrs** | Per RDV | cost | € 100.80 |  | € 0.00 | Pro rata |
| **TEC examination time for screening patient** Preparation of the visits: organisation and scheduling of acts within protocol, hospitalisation, etc., informing the patient about the practical aspects of the research visits. Completion of CRF including recital of patient's antecedents, retrieval of source data, query resolution. **Level 1:** 1h + 15min per 10 pages of CRF **Level 2:** 2 hr +15min per 5 pages of CRF (reason: modification of course of care by implementation of the research). **Level 3:** 3h + 15min per 5 pages of CRF *List the visits* | Per examination | cost | level 1: € 50.4  level 2: € 100.8  level 3: € 151.2 | 1 |  |  |
| **TEC on-site examination time for patient or telephone follow-up**  Organisation of examination (including organisation and scheduling of acts within the protocol, hospitalisations, etc.), use of CRF, answering queries, Management of undesirable events, State which with aid of protocol. **Level 1:** 1h + 15min per 10 pages of CRF **Level 2:** 2h + 15min per 5 pages of CRF **Level 3:** 2h + 15min per 5 pages of CRF *List the visits* | Per examination | cost | level 1: € 50.4  level 2: € 100.8  level 3: € 100.8 |  |  |  |
| **Final TEC examination time or premature cessation** Preparation of examination (including organisation and scheduling of acts within the protocol, hospitalisations, etc.), use of CRF, answering queries. **Level 1:** 1h + 15min per 10 pages of CRF **Level 2:** 2h + 15min per 5 pages of CRF **Level 3:** 2h + 15min per 5 pages of CRF *List the visits* | Per examination | cost | level 1: € 50.4  level 2: € 100.8  level 3: € 100.8 | 1 |  |  |
| **TEC training time for questionnaires and patient notes -** 1 hr/protocol | Per trained personnel | cost | € 50.40 |  | € 0.00 | € 0.00 |
| **TEC management time for self-questionnaire or entry and completion of patient questionnaires -** 15 min per patient  if > 5 self-questionnaires 30 min per patient *List the visits* | Per examination | cost | €12.6  if > 5 self-questionnaires: € 25.2 |  |  | € 0.00 |
| **TEC time for initial patient training in the self-questionnaire:** electronic (1hr/patient) / paper (30min/patient)if > 5 self-questionnaires: electronic (1 hr 30/patient) / paper (45 minutes/patient) | Per patient | cost | electronic €50.4paper € 25.2if > 5 self-questionnaires electronic €75.6paper € 37.8 |  |  | € 0.00 |
| **TEC time for management of sampling kits.** 1h/ visit with centralized sampling. *List the visits* | Per examination | cost | € 50.40 |  | € 0.00 | € 0.00 |
| **TEC time IVRS/IWRS call** *List the visits* | Per call | cost | € 10.00 |  | € 0.00 | € 0.00 |
| **TEC time for managing patient travel reimbursements**20 min if the intervention is done without the use of a platform50 min if the intervention is done via a platform*List the visits* | Per examination | cost | without platform: € 16.8with platform: € 42 |  |  |  |
| **Estimation of nursing time - € 45.6/hr** | | | | | | |
| Existing nomenclatures include current patient care Nursing time added enhances the realisation of these acts in the restricted framework of the protocol exceeding standard practice: => compliance with requirements of protocol; => compliance with requirements of laboratory manual; => use of specific kits for protocol; => completing forms for protocol, etc. Use of AMI pricing. | | | | | |  |
| **Nurse time to draw blood for central analysis -** 15min *List the visits* | Per examination | cost | € 11.40 |  | € 0.00 | € 0.00 |
| **Nurse time to collect urine for central analysis -** 15min *List the visits* | Per examination | cost | € 11.40 |  | € 0.00 | € 0.00 |
| **Nurse time to measure vital signs -** 15min *List the visits* | Per measurement of vital signs | cost | € 11.40 |  | € 0.00 | € 0.00 |
| **Nurse time for study treatment injection** - 15min *List the visits* | Per injection | cost | € 11.40 |  | € 0.00 | € 0.00 |
| **Nurse time for infusion insertion and removal -** 30min *List the visits* | Per insertion and removal | cost | € 22.80 |  | € 0.00 | € 0.00 |
| **Nurse time for catheter insertion and removal -** 30min *List the visits* | Per insertion and removal | cost | € 22.80 |  | € 0.00 | € 0.00 |
| **Nurse time to assist the doctor in performing a technical or other procedure** | Per examination | cost |  |  | € 0.00 | € 0.00 |
| **Nursing time per PK/PD point** - 15min  *List the visits* | Per PK/PD point | cost | € 11.40 |  | € 0.00 | € 0.00 |
| **NOMENCLATURAL ACTS** | | | | | | |
| **Act** *List the visits* |  | additional cost |  |  | € 0.00 | € 0.00 |
| **ECG** (DEQP003) *List the visits* | Per examination | additional cost |  |  | € 0.00 | € 0.00 |
| **Blood samples -** 1.5 AMI *List the visits* | Per sampling | additional cost |  |  | € 0.00 | € 0.00 |
| **Urine samples -** 1 AMI *List the visits* | Per sampling | additional cost |  |  | € 0.00 | € 0.00 |
| **NON-NOMENCLATURAL ACTS CLINICAL SERVICES AND MEDICAL TECHNIQUES** | | | | | | |
| **Act** *List the visits* |  |  |  |  | € 0.00 | € 0.00 |
| **HOSPITALISATION AND CONSULTATIONS** | | | | | | |
| **Additional medical consultation** Specific to the research *List the visits* | Per consultation | additional cost | Price for CAM  CS or CNPSY or CSC |  |  | € 0.00 |
| **Fixed hotel accommodation costs > 24hs**  For meals, room, heating, fluids, technical services, medical and nursing care time (fixed costs other than compensation for additional acts associated with daytime research) => fixed costs must correspond to actual occupation required by the protocol, for bed, chair: occupation is not systematic. the fixed costs take into account 1 hour of medical time + 1 hour of nursing time + meal.  *List the visits* | Fixed fee per examination | additional cost | € 355.00 |  | € 0.00 | € 0.00 |
| **Fixed hotel accommodation costs > 24hs**  For meals, room, heating, fluids, technical services, medical and nursing care time (fixed costs other than compensation for additional acts associated with daytime research) => fixed costs must correspond to actual occupation required by the protocol, for bed, chair: occupation is not systematic. the fixed costs include 2 hours of medical time + 2 hours of nursing time + meal.  *List the visits* | Fixed fee per examination | additional cost | € 666.00 |  | € 0.00 | € 0.00 |
| **OTHER COSTS / ADDITIONAL COSTS ATTRIBUTABLE TO RESEARCH** | | | | | | |
| **Any unforeseen additional costs, attributable to the research** |  | cost |  |  | € 0.00 | If applicable |
| **Fixed costs for undesirable serious event (EIG) attributable to the research**: (managed outside follow-up examinations) - 1 hr TEC time and 20min medical time. | Per EIG | cost | € 84.40 |  | € 0.00 | Pro rata |
| **Medical time** Medical time exceeding current practice: training, specific examination, telephone monitoring and not included for acts done in relation to research, per hour.*List the visits* | Per patient | cost | € 102.00 |  | € 0.00 | € 0.00 |
| **Research closure fixed cost Level 1:** 30 min medical time + 2h TEC time  **Level 2:** 30 min medical time + 3h TEC time  **Level 3:** 1 hour of medical time + 3 hours of TEC time. | Fixed cost per research | cost | level 1: € 151.8 level 2: € 202.2 level 3: € 253.2 |  |  | € 0.00 |
| **Reagents and consumables:** required by the protocol. Excluding routine analyses. Invoice or fixed costs / per visit. | Per line | cost |  |  | € 0.00 | € 0.00 |
| **BIOLOGY - ANATOMO-PATHOLOGY** | | | | | | |
| **Biology/pathology coordination research time**  Contribution to: selection, verification of the coordinating matrix: information, placing of flag, modifications of practices, results, etc. Training for laboratory manual. 1 hr 30/coordinating or associated centre (if required from sponsor). | Per centre | cost | € 75.60 | 1 | € 75.60 | € 75.60 |
| **Biology/Pathology Research Time** Transmission of documents (CV, VR, CQ, if cryo-conservation: CT (Temperature curves), CS (calibration surveys), CM (Metrological and Maintenance Inspections). 1 hr 30 (if required by the protocol). | Per centre | cost | € 75.60 | 1 | € 75.60 | € 75.60 |
| **BIOLOGY - Nomenclatural Act - NABM RIHN** | | | | | | |
| **Nomenclature:** description of analyses, panel with NABM code and individual or global listing. *List the visits* | Per assessment | additional cost |  |  | € 0.00 | € 0.00 |
| **Fixed costs for security (9105) and Pre-Analytical Package (9005) - B22**  *List the visits* | 1 time/day/patient | additional cost |  |  | € 0.00 | € 0.00 |
| **BIOLOGY - Act outside NABM RIHN** | | | | | | |
| **Tech Labo Time. Management and technology of biological samples;** centrifugation, aliquoting, freezing, traceability as well as preparation of ambient and dry ice shipments the same day (1h).  *List the visits* | Per examination | additional cost | € 50.40 |  | 0 | € 0.00 |
| **Tech Labo Time. Management and technology of PK blood samples.** Preparation and sending to the centralized lab chosen by the sponsor 30min/kinetic KP point from 2 points in a single visit. *List the visits* | Per PK point | additional cost | € 25.20 |  | € 0.00 | € 0.00 |
| **Tech Labo Time. Specific preparation** (if preparation required in the protocol, to be assessed according to research). *List the visits* |  | cost |  |  | € 0.00 | € 0.00 |
| **Fixed costs for conservation for research** Storage and exit whatever kind of sample (serum plasma, urine, DNA, etc.) if required by the protocol. To be evaluated in proportion to the number of years. | Annual fee | cost | € 200.00 |  | € 0.00 | € 0.00 |
| **Time to set up an activity, outside the routine circuit, required by research in a specialised laboratory.** Biologist time: 4 hrs  Tech labo time: 4 hrs | Per specialty/research laboratory | cost | € 609.60 |  | € 0.00 | € 0.00 |
| **Time to set up a "Central Lab" activity at the Biology/CRB centre**Tech labo time: 9 hrs | Per specialty/research laboratory | cost | € 453.60 |  | € 0.00 | € 0.00 |
| **Coordination time for the implementation in an on-call service**: mep meeting, drafting of flag and procedure, training  TEC coord time: 8 hrs  Tech labo time form: 6 hrs x 2 | Per centre accepting this specificity  (at the explicit request of the sponsor)  If applicable | cost | € 1,008.00 |  | € 0.00 | € 0.00 |
| **ANATOMO-PATHOLOGY - Act with ACPC nomenclature** | | | | | | |
| Act | Per act | additional cost |  |  | € 0.00 | € 0.00 |
| **ANATOMO-PATHOLOGY - Act without ACPC nomenclature** | | | | | | |
| **Preparation and despatch fresh or archived biopsy for** **centralised re-reading** Identification of blocks, preparations of slides (white or coloured) management of despatch forms (completion and ordering). *List the visits* | Per block or biopsy sent | additional cost | € 150.00 |  | € 0.00 | € 0.00 |
| **ACP doctor time: expertise; selection of the block and the area of interest of the biopsy before processing and sending to the central lab.** *List the visits* | Per examination 1 hr 30 | Cost | € 153.00 |  | € 0.00 | € 0.00 |
| **Tech labo time. Specific preparation** (if preparation required in the protocol, to be assessed according to research). *List the visits* |  | cost |  |  | € 0.00 | € 0.00 |
| **Tech labo specific preparation time: Slides if >20** *List the visits* | Per batch of 5 slides (over 20) | Cost | € 10.00 |  | € 0.00 | € 0.00 |
| **Fixed costs for de-archiving tumour blocks from an external laboratory** (€50 or if > €50 actual on presentation of an invoice). | Per de-archiving | cost |  |  |  |  |
| **IMAGING** | | | | | | |
| **Fixed price for setting up imaging research** 4hr TEC time + 1hr medical time | Per centre | cost | € 303.60 |  | € 0.00 | € 0.00 |
| **Fixed cost for complex Imaging**  If the protocol requires specific imaging expertise. On proof. | Per centre | cost |  |  | € 0.00 | € 0.00 |
| **Re-reading of examination realised outside centre -** 30 min medical time. | Per examination | cost | € 51.00 |  | € 0.00 | € 0.00 |
| **Fixed costs for specific maintenance** (if not already included) | Per equipment if applicable under the protocol | cost | € 100.00 |  | € 0.00 | If applicable |
| **Specific tasks for imaging expertise: anonymisation/engraving of data and CD**30 min Clinical research technician (TEC) time *List the visits* | Per examination | cost | € 25.20 |  | € 0.00 | € 0.00 |
| **Clinical research technician time**: **Sending of images via internet platforms or via DVD and transmission of DTF (data transmittal form) -** 30 min Clinical research technician (TEC) time *List the visits* | Per examination | cost | € 25.20 |  | € 0.00 | € 0.00 |
| **Nomenclatural Acts** | | | | | | |
| **Standard examination** = ACPC base + maximum technical fee + modifier + digital archiving fee + medications or diagnostic agent *List the visits* | Per examination | additional cost |  |  | € 0.00 | € 0.00 |
| **Examination longer than standard or with additional sequences or incidences or with specific post-treatment** = (ACPC base + maximum technical fee + modifier) x additional time/average duration + medications or diagnostic agent  *List the visits* | Per examination | additional cost |  |  | € 0.00 | € 0.00 |
| **Non-nomenclatural Acts** | | | | | | |
| **Examination without basic ACPC = actual cost** *List the visits* | Per examination | additional cost | actual cost |  |  | € 0.00 |
| **Additional medical time** **for complex imaging research requiring a non-standard patient pathway -** 1 hour of medical time | Per centre | cost | € 102.00 |  | € 0.00 | € 0.00 |
| **Additional TEC time for complex imaging research requiring a non-standard patient pathway -** 4 hours of TEC time | Per centre | cost | € 201.60 |  | € 0.00 | € 0.00 |
| **TEC time**: **uploading images made outside the centre to PACS and managing the file** - 30min TEC time | Per examination If applicable | cost | € 25.20 |  | € 0.00 | € 0.00 |
| **TEC monitoring time with sponsor/CRO: preparation of patient files, site visit -** 2 hr 30 of TEC time per monitoring visit | Per follow-up If applicable | cost | € 126.00 |  | € 0.00 | € 0.00 |
| **TEC time for queries -** 15 min TEC time per examination | Per examination | cost | € 12.60 |  | € 0.00 | € 0.00 |
| **TEC time** **for the management of samples taken under imaging -** 1 hr/sample (if not included in the anatomical pathology section). List the visits | Per sample If applicable | cost | € 50.40 |  | € 0.00 | € 0.00 |
| **TEC time for CRF entry -** 15 min/5 completed CRF pages | 5 completed CRF pages | cost | € 12.60 |  | € 0.00 | € 0.00 |
| **Medical time: Post-processing tasks (reconstructions, measurements, etc.) -** 30min medical time  *List the visits* | Per examination If applicable | cost | € 51.00 |  | € 0.00 | € 0.00 |
| **Medical time for imaging expertise at the request of the sponsor and within the framework of the protocol: know-how, intellectual investment, intellectual fixed costs according to a scale and quality indicators = all examinations including examinations carried out externally -** 1 hour of medical time*List the visits* | Per examinationIf applicable | cost | € 102.00 |  | € 0.00 | € 0.00 |
| **PHARMACY - RADIOPHARMACY - MEDICAL DEVICE** | | | | | | |
| **Pharmaceutical or radiopharmaceutical fixed costs 1st year** | Per centre | cost | € 500.00 | 1 | € 500.00 | € 500.00 |
| **Pharmaceutical or radiopharmaceutical fixed costs - additional year** In proportion to the number of additional years. | Per centre | cost | € 200.00 |  | € 0.00 | € 0.00 |
| **Fixed costs for nominative dispensing** *List the visits* | Per dispensing line | cost | € 28.00 |  | € 0.00 | € 0.00 |
| **Destruction** | With the flow | cost | € 8.00 |  | € 0.00 | Pro rata |
| **Implementation of destruction** | Per campaign | cost | € 80.00 |  | € 0.00 | Pro rata |
| **Special conditions for conservation** | Per storage area | cost | € 50.00 |  | € 0.00 | € 0.00 |
| **Labelling or re-labelling** | <10 units | cost | € 15.00 |  | € 0.00 | Pro rata |
| **Labelling or re-labelling** | between 10 and 50 | cost | € 25.00 |  | € 0.00 | Pro rata |
| **Labelling or re-labelling** | >50 | cost | € 50.00 |  | € 0.00 | Pro rata |
| **Follow-up monitoring visit** | Per examination | cost | € 30.00 |  | € 0.00 | Pro rata |
| **IVRS (random patient selection) or @VRS acts**  All acts: reception, dispensation, returns and other acts validated by this method are concerned, including allocation of treatment to patient. | Per act | cost | € 10.00 |  | € 0.00 | € 0.00 |
| **Reception/delivery** | Per reception/ delivery | cost | € 20.00 |  | € 0.00 | Pro rata |
| **Allocation of treatment to patient** (call from a vocal server - IVRS) | Per call | cost | € 10.00 |  | € 0.00 | € 0.00 |
| **Reconstitution/preparation of medications/assembly of MD non-sterile conditions MED and/or MD**  *List the visits* | Per act | cost | € 20.00 |  | € 0.00 | € 0.00 |
| **Reconstitution/preparation of medications/assembly of MD sterile conditions MED and/or DM** *List the visits* | Per act | cost | € 60.00 |  | € 0.00 | € 0.00 |
| **Constitution + sterilisation of a standardised facility (DM)**  *List the visits* | Per facility | cost | € 60.00 |  | € 0.00 | € 0.00 |
| **Audits (including preparation time)** Not for inspections by competent authorities. Not applicable for DM. | Per audit | cost | € 300.00 |  | € 0.00 | If applicable |
| **Specific traceability**Single fixed sum of 70 € for whole research: MDS, DMI and drugs. | Per centre | cost | € 70.00 |  | € 0.00 | € 0.00 |
| **Referencing and use of protocol in prescription software** (solely case by case on proof if complex reconstitution of products at the research (e.g..: cytotoxics, monoclonal antibodies). | Per centre | cost | € 150.00 |  | € 0.00 | € 0.00 |
| **Supply of health product** Purchase of pharmaceutical product: purchase price and pharmacist time (purchase, supply, pharmaceutical management of the investigational or non-investigational medications or DM). | Per order line  or per complete system for a DM | additional cost |  |  | € 0.00 | € 0.00 |
| **Pharmacy - non-nomenclatural acts** | | | | | | |
| **Training** (based on pharmacist time or TEC/PPH time). | Per trained personnel | cost |  |  | € 0.00 | € 0.00 |
| **Storage/archiving for PUI** (€10 /regulatory year). |  | cost |  |  | € 0.00 | € 0.00 |
| **TOTAL** |  |  |  |  |  | **€ 0.00** |
|  |  |  |  |  |  |  |

### Appendix 2.2

|  |  |  |
| --- | --- | --- |
| Invoicing procedures within the Establishment | | |
|  |  |

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*. *See the example below:*

*Receipts must be made out to (choose the appropriate item):*

*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 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 banking coordinates for the Establishment]

### 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 controller 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.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Appendix 4 [optional] | | | |  |
| Definition of the Counterparts  specific optional appendix for each health establishment, care home or health centre participating in the research | | | | |
|  |  | | |  | |
| **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** | | |
|  |  |  | | |
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|  |  |  | | |
|  |  |  | | |
|  | **Total** |  | | |

**Invoicing procedures within the Third-party Structure:**

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 banking coordinates for the Third-party Structure]

### Appendix 5 [optional]

|  |  |  |
| --- | --- | --- |
| Agreement for provision of equipment and/or biological samples | | |
|  |  |