**Sole agreement**

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

**concerning the implementation of the**

**commercial research Protocol involving the human person**

Clinical Trial No.

 **EudraCt no.…….. or Idrcb no.………**

***Coordinating Establishment Version***

BETWEEN THE UNDERSIGNED:

**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“;

of the one 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“;

**of the other part,**

**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 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 and, where appropriate, the Third-party structure, are hereafter referred to individually as the “Party“ or collectively as the “Parties“.

**Having considered:**

- articles L.1121-16-1 and R.1121-4 of the French Public Health Code (CSP);

- the clinical Good Practice rules **of 24 November 2006**;

- the code of medical ethics (articles R.4127-1 to R.4127-112 of the French Public Health Code);

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

WHEREAS:

The Company has decided to conduct the research 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;
* [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 health Establishment before the opening of the centres;
* [if the authorisation has been obtained] is registered under no. \_ \_ \_ \_ \_ \_ \_\_ \_ \_ \_ \_ \_ \_ and authorised on\_ \_ \_ \_ \_ \_ \_\_ \_ \_ \_ \_ \_ \_ by the French National Agency for the Safety of Medications and Health Products (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\_ \_ \_ \_ \_\_ \_ \_ \_ \_ \_ ;
* 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**

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 or health centre making 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 or health centre 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 CSP.

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 3.

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 Coordinating 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 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.

**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 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).

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.

## 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 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 *force majeure*.

**CLAUSE 11: ANTI-CORRUPTION - TRANSPARENCY**

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 L1453-1 of the French Public Health Code, the Company is bound to make public the existence of the agreement and its benefits.

Processing of personal data with a view to such publication shall be effected pursuant to the French Data Protection law of 6 January 1978, as amended.

The Coordinating Investigator has a right of access to and rectification of any information concerning him.

**CLAUSE 12: DISPUTES**

This agreement is subject to French law.

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 [Optional] – consideration for conducting the Research;

• Appendix 4 [Optional] – agreement for provision of equipment.

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

In X original counterparts.

 Per pro/ the Coordinating health Establishment Per pro / 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 or the \_ \_ \_ \_ \_ \_ health establishment.

*"I have read and understood this Agreement"*