

**CONTRACT FOR CONDUCTING CLINICAL INVESTIGATION
ON A MEDICAL DEVICE NOT EC MARKED OR EC MARKED BUT USED OUTSIDE THE SCOPE OF ITS
INTENDED USE
[Name of medical device]
CLINICAL INVESTIGATION “ ___ ”**

BETWEEN

___ (*please indicate the name of the health structure*) henceforth called “Institution”, with registered office in ___ Tax Code and VAT No. ___, in the person of the Legal Representative, ___, as ___ (*please indicate if General Manager, Chief Executive Officer, Extraordinary Commissioner, etc.*), who has appropriate powers to sign this Act on ___ (*qualification of the signatory*),

AND

(a) (*in case of signing with the Sponsor*)

___ (*please indicate the Sponsor*) with registered office in ___, Tax Code no. ___ and VAT No. ___, in the person of the Legal Representative ___, as ___, (hereinafter referred to as “Sponsor”)

(a1) in the case of a clinical investigation whose Sponsor is not established in the European Union and concluded by its representative in the territory of the latter):

___ (*indicate the Company representing the Sponsor in the European Union*), with registered office in ___ Tax Code No. ___ and VAT No. ___, in the person of the Legal Representative ___, as a Company representative of the Sponsor in the European Union pursuant to Art. 62, paragraph 2 of Regulation (EU) 2017/745_ (hereinafter referred to as the “Company”), which, by virtue of a specific mandate given on ___, is responsible, in accordance with Regulation (EU) 2017/745 (hereinafter “the Regulation”), to ensure compliance with the obligations of the Sponsor of the clinical investigation ___ with registered office in ___, VAT No. ___ (hereinafter referred to as “Sponsor”)

Or,

(B) *in case of assignment to a CRO or to a legal representative also for the stipulation)*

___ (*indicate the CRO, the legal representative or in any case the subject with the appropriate power of representation*), with registered office in ___, Tax code No. ___ and VAT No. ___, in the person of the Legal Representative ___ as ___, (hereinafter referred to as “CRO/legal representative”), acting in the name and on behalf of/in the name of/in the interest of ___, (hereinafter referred to as “Sponsor”), by virtue of appropriate delegation/mandate/procurement conferred on ___

below for brevity individually/collectively “Part(s)”

Provided that:

A. it is the Sponsor's interest to carry out the clinical investigation of medical device entitled: "___" (hereinafter "Clinical Investigation"), concerning Protocol No ___ version of ___ and subsequent amendments duly approved (hereinafter "Protocol"), Eudamed Code No. ___, at ___ the Institution, under the responsibility of Dr./Prof. ___, as Scientific Manager of the clinical investigation subject to this Agreement (hereinafter referred to as the "Principal investigator"), at ___ (*indicate the Operational Unit/Department/etc.*) (hereinafter referred to as the "Trial Centre");

B. the Sponsor identifies as its own scientific contact for the part of its competence Dr./Prof. ___. The Sponsor may modify the scientific contact person for the part within its competence with written notification to the Institution;

C. the Trial Centre has the technical and scientific expertise for the clinical investigation and is a structure appropriate to conduct the clinical investigation in compliance with current legislation;

D. the Principal investigator and his/her direct collaborators, qualified under the Protocol to act with discretionary powers in the execution of it (hereinafter "Co-investigators"), as well as all other subjects who carry out any part of the clinical investigation under the supervision of the principal investigator, are suitable for conducting the clinical investigation in accordance with applicable legislation, they know the protocol and standards of good clinical practice and have the required legal and regulatory requirements, including those concerning compliance with current legislation concerning conflict of interest;

E. except as otherwise agreed in writing by the Parties, the Institution shall conduct the Clinical Survey exclusively at its own facilities;

F. *(I) (In case loan for use of equipment is **not** required)*

the Institution is equipped with suitable equipment to conduct the clinical investigation as indicated in the Protocol;

Or,

(II) (In case loan for use of equipment is required)

the Institution, despite being equipped with equipment suitable for conducting the Clinical Investigation, receives from the Sponsor loan for free use, pursuant to the Civil Code, of the equipment and/or assets essential for the success of the Clinical Investigation, listed in Art. 5 of this Agreement;

G.

(I) (If the device is not EC-marked and belongs to class I, IIa or IIb excluding invasive devices)

The Sponsor, pursuant to Art. 70 of the Regulation submitted to the Ministry of Health (hereinafter referred to as "Competent Authority") an application for a clinical investigation on the device without the EC mark, on ___, and on ___ the Ministry validated the application;

(II) (If the device is not EC-marked and belongs to class III, or is an invasive device belonging to classes IIa and IIb)

The Sponsor has received authorisation from the Ministry of Health to carry out the clinical investigation by written note on ___;

H. (i) (In case the Institution is the Coordinating Centre in Italy):

on ___, the Ethics Committee responsible for the Institution, as the Coordinating Centre in Italy for the study, expressed a single opinion in favour of carrying out the clinical investigation at the Institution;

Or,

(II) (If the Institution is not the Coordinating Centre in Italy)

pursuant to Art. 7 of Legislative Decree No. 211 of 24 June 2003, on ___, the Promoter obtained the Single Opinion in favour of carrying out the Clinical Investigation by the Ethics Committee ___, the Ethics Committee Coordinating the Investigation for Italy on ___ and the relevant Ethics Committee has expressed its opinion in favour of conducting the Investigation, accepting the Single Positive Opinion referred to above;

I. (if this is the case) in the negotiation of this Contract the Parties have based themselves on the scheme approved by the National Coordination Centre of Territorial Ethics Committees pursuant to Art. 2(6) of Law no. 3 of 11 January 2018 and, in compliance with the homogeneity of the administrative, economic and insurance aspects referred to therein, have decided to supplement and/or amend the relevant provisions, in order to regulate the specificities and peculiarities of the Investigation, on the basis of the following reasons (→ please specify):

J. The Sponsor has taken out insurance policy as specified in the following Art. 8 of this Agreement.

The Parties agree and stipulate the following:

Art. 1 — Entirety of the Agreement

1.1 The premises, the Protocol, even if not materially enclosed, and all annexes, including the budget (Annex A) and the Glossary on Personal Data Protection (Annex B) are an integral and substantial part of this Agreement.

Art. 2 — Subject matter

2.1 The Sponsor entrusts to the Institution the conduct of the Clinical Investigation under the conditions set forth in this Agreement, in accordance with the Protocol, with any subsequent amendments as well as with the amendments to this Agreement/budget resulting from them and formalised by the necessary acts of modification promptly signed.

2.2 The clinical investigation must be conducted in the most scrupulous respect of the Protocol, in the current version, accepted by the Principal investigator, approved by the Ethics Committee and the Competent Authority, in accordance with the current legislation on clinical investigations on medical devices and the Ethics principles that inspire the medical activity of professionals involved in various ways.

2.3 The clinical investigation must also be conducted in accordance with the principles contained in the Convention on Human Rights and Biomedicine, in the updated version of the Helsinki Declaration, in the current rules of Good Clinical Practice, in accordance with the applicable laws on transparency and prevention of corruption, as well as with protection of personal data pursuant to current legislation.

2.4 By signing this Agreement, the Parties declare that they know and accept the content of the above mentioned.

2.5 The Sponsor and the Principal Investigator, having the obligation to protect patients' health, when the circumstances apply, may adopt urgent and adequate measures to protect patients' safety, such as the temporary suspension of the study (interruption of treatment for patients already involved in the clinical investigation or interruption of the inclusion of new subjects), in accordance with the procedures provided for in Art. 77 of the Regulation, without prejudice to the obligation for the Sponsor to immediately inform the Ethics Committee and the Competent Authority, as well as the participants in the study about new events, the measures taken and the program of measures to be taken, promptly completing the procedures provided for in the current legislation. The Sponsor, having been notified by the investigator of an accident or a serious adverse event for which there is a causal relationship even if reasonably possible with the device under investigation, the product of comparison or the investigation procedure, shall promptly notify the Ministry of Health and the competent Ethics committees, pursuant to the provisions of Art. 80 of the Regulation.

2.6

(a) In case of non-competitive inclusion of patients

The Institution plans to include indicatively no. ___ patients by ___ (*insert estimated date*). The Parties acknowledge that any increase in the number of patients to be involved at the Trial Centre of the Institution shall be agreed in advance between the Parties and forwarded to the Ethics Committee and, if applicable, to the Competent Authority as a substantial amendment. It is understood that the increase in the records, carried out under these conditions, does not require the conclusion of an additional act to this Agreement, where the economic conditions for patients agreed therein apply to all additional patients.

Or

(b) In case of multicentre clinical investigation with competitive inclusion

Since the Clinical investigation provides for the competitive inclusion of patients, the Institution is expected to include approximately ___ subjects, with the limit of the maximum number of ___ patients eligible for the Clinical investigation globally and within the terms provided by the Sponsor.

The expected period of inclusion is subject to changes depending on its performance also at an international level. Upon reaching the total number of patients expected for the entire Clinical investigation, the inclusion of additional patients will be automatically closed, regardless of the number of patients included by the Institution, except for patients who have already given their consent to participate in the clinical investigation, unless they withdraw consent. The Sponsor will send appropriate and timely communication to the Institution.

2.7 The Institution and the Sponsor shall keep the documentation relating to the clinical investigation (permanent "*trial master file*") for the period of time according to the specifications indicated by the current legislation (or for a longer period, if this is required by other applicable rules or by an economic agreement between the Institution and the Promoter). The Sponsor is

obliged to inform the Experimental Centre of the expiry of the retention obligation. Upon request by the Sponsor, after the expiry of the aforementioned deadline, the Parties may agree on the conditions of a further retention period, making the data anonymised in advance.

2.8 The Institution and the Sponsor, each for the areas of its own competence, also undertake to maintain the abovementioned documentation by adopting forms of documentary digitisation (or dematerialisation). Regardless of whether or not the archiving of the documentation concerning the clinical investigation concerns personal data (of a particular nature or not), according to the definitions of Regulation (EU) 679/2016 (hereinafter, "GDPR"), the Institution and the Sponsor must take all the physical and technical measures referred to in Art. 32 of the GDPR and carry out any security checks provided for by current legislation to protect data, information and documents (in both paper and electronic form). The storage system adopted must ensure not only the integrity of the data, information and paper and electronic documents, but also their future readability for the entire period required by the retention obligation. For the fulfilment of this obligation, both the Sponsor and the Institution may make use of external parties to manage this archiving obligation.

2.9 The Sponsor, the Institution and the Principal Investigator must comply with the directives, indications, instructions and recommendations of the Ethics Committee and of the competent authority.

Art. 3 — Principal investigator and co-investigators.

3.1 The Principal investigator will be assisted in performing the clinical investigation by direct collaborators, qualified under the Protocol to act with discretionary powers in the execution of it (hereinafter "Co-investigators"), as well as by healthcare and non-healthcare staff appointed by the Institution. Co-investigators and other staff will operate under the responsibility of the Principal investigator; they must be qualified to conduct the investigation, have received prior training from the Sponsor in accordance with current legislation and have indicated their willingness to participate in the clinical investigation.

3.2 The Parties acknowledge that the Principal investigator is bound by all responsibilities and obligations imposed on this figure by current legislation on clinical investigations of medical devices.

3.3 This relationship exists between the Sponsor and the Institution. The Sponsor is foreign to the relationships existing between the Institution, the Principal Investigator, the Co-investigators and all the other personnel participating in the Clinical Investigation, thus remaining relieved of any claim that they should make related to the clinical investigation.

3.4 In relation to the investigation covered by this Agreement, the Parties acknowledge that they have complied with the provisions of Art. 6(4) of Legislative Decree no. 52 of 14 May 2019, as amended by Art. 11-bis of Law no. 77 of 17 July 2020, converting Legislative Decree no. 34 of 19 May 2020 ("Decreto Rilancio").

3.5 Should the relationship between the Principal Investigator and the Institution terminate for any reason, the Institution must promptly inform the Sponsor in writing, indicating the name of a substitute. The indication of the substitute must be approved by the Sponsor and the relevant Ethics Committee. The Institution warrants that the new Principal Investigator has the appropriate requirements to continue the clinical investigation, accepts the terms and conditions of this Agreement and undertakes to comply with the Protocol in conducting the clinical investigation.

Pending approval of the change amendment of the Principal investigator, the Investigator indicated by the Sponsor guarantees the necessary continuity of the investigating activity. In the event that the Sponsor does not intend to accept the name of the replacement proposed by the Institution or the latter does not propose a substitute, the Sponsor may terminate this Agreement in accordance with the provisions of Art. 7.

3.6 The Principal investigator must acquire the informed consent of the patient or his/her legal representative, in accordance with the provisions of the current legislation on clinical investigations and consent to the processing of personal data pursuant to the current national and EU legislation on the protection of personal data, as subsequently provided for in Art. 11.

3.7 The Principal Investigator must record and document detailed records of all adverse events and serious adverse events and to notify the Sponsor in accordance with current legislation. In addition, the Principal investigator must provide any other clinical information relevant to the conduct of the study indicated in the Protocol (e.g. pregnancy) directly or indirectly related to conducting the clinical investigation, in accordance with the Protocol, the rules of Good Clinical Practice and the applicable legislation on device-vigilance and clinical investigations of medical devices and, where applicable, on pharmacovigilance and clinical trials of medicinal products.

3.8 The Institution will ensure that the principal investigator also undertakes to ensure that the clinical investigation is carried out according to the highest standards of diligence. In particular:

3.8.1 The Principal investigator must deliver all the Case Report Forms (CRFs) correctly completed, according to the terms and methods provided for by the Clinical Investigation Protocol and the applicable legislation, in paper or electronic format, and in any case with timeliness as per GCP, within the deadlines provided for by the Clinical Investigation Protocol.

3.8.2 The Principal investigator also undertakes to resolve requests for clarification (queries) generated by the Sponsor within the deadlines provided for in the Clinical Investigation Protocol.

3.8.3 To verify the correspondence between the data recorded in the Case Report Forms and those contained in the original documents (e.g. medical records), the Institution and the Principal Investigator allow direct access to the original data during monitoring visits and during any audits promoted by the Sponsor and inspections by the Competent Authorities, including remote procedures, provided that the rules are not violated on confidentiality and protection of patients' personal data.

3.8.4 The Institution and the Principal Investigator, informed with appropriate notice, must allow the proper conduct of monitoring and auditing and inspections at the Trial Centre ___ by the Sponsor's staff, and by the Competent Authority, activities carried out to ensure the regular performing of the clinical investigation.

3.9 (Where appropriate, taking into account the current rules on the protection of personal data) Acknowledging the favourable assessment of the competent structure the software ___ (indicate the name of the software) will be provided free of charge. With reference to the same, it is understood that:

3.9.1 For the use of network infrastructures and IT systems, the Sponsor undertakes to agree on the methods of installation and delivery of the product, subject to the issue by the competent local structure of a declaration of verification with positive results on the feasibility, technical compatibility with the standards in place in the Institution and sustainability in the medium term with respect to the services already in operation.

3.9.2 In the same way, the Sponsor undertakes to uninstall the product at the end of the study, without charge for the Institution.

3.9.3 The Sponsor warrants that the use by the Institution of the abovementioned products as part of the study does not give rise to any obligation for the Institution to purchase or subscribe to supplies or services from the Sponsor, that it does not infringe any third party's licenses or rights, and that it does not commit the Institution to use the product beyond the terms set forth in the study as provided by this Agreement.

3.9.4 The Sponsor also warrants that the use of the product in the context of the study does not entail for the Institution any assistance, modification or updating of the IT network in all its hardware/software components and therefore does not result in a breach of contractual obligations towards the direct suppliers of the Institution.

3.9.5 In any case, the Sponsor indemnifies the Institution from direct or indirect damages resulting from the use of the product in accordance with the manufacturer/supplier's instructions.

3.10 The Institution shall promptly notify the Sponsor, if a Competent Authority communicates to the Institution an inspection/audit notice relating to the clinical investigation and, if not expressly denied by the Competent Authority, the Institution will authorise the Sponsor to participate, while sending to Sponsor any written communication received and/or transmitted for the purposes or as a result of the inspection/audit.

3.11 However, these activities must in no way affect the performance of the Institution's ordinary activity.

3.12 The Institution or Sponsor warrants that the biological samples (blood, urine, saliva, etc.) of the patients involved in the clinical investigation referred to in this Agreement will be used exclusively for the clinical investigation covered by this Agreement, in accordance with the provisions of the Protocol and current legislation. Any storage and subsequent use are bound to the acquisition of a specific informed consent by the patient (or the parent/legal guardian), to the favourable opinion of the Ethics Committee, within the limits and with the guarantees provided by the regulations in force and the guidelines referred to in Art. 1 of Legislative Decree No. 52 of 14 May 2019.

Art. 4 — Medical devices for clinical investigation and materials

4.1 The Sponsor undertakes to provide the Institution, free of charge, for the duration of the Clinical investigation and in the quantities necessary and sufficient for the execution of the Clinical investigation, the Medical Devices subject to the Clinical investigation (___) (hereinafter "Medical Devices for the Clinical investigation").

The reception and tracking of experimental devices must take place with the registration of the batches. The Sponsor undertakes to provide any other material necessary for the conduct of the Clinical investigation (hereinafter referred to as "Materials").

The quantities of Medical Devices for the Clinical Investigation should be adapted to the number of cases treated.

4.2 Medical Devices and Clinical Investigation Materials must be sent by the Sponsor, at its own expense, to the competent Organisational Unit identified by the Institution, which will arrange for their registration, appropriate storage and delivery to the Principal investigator as provided for in the Protocol and current legislation.

4.3 Medical devices for the clinical investigation must be provided with an appropriate transport document intended for the competent Organisational Unit of the Institution, with a description of

the type of medical device, its quantity, the preparation batch, the storage requirements, the expiry date and the references to the Clinical investigation (Protocol Code, Principal investigator and the Trial Centre concerned).

4.4 The Institution and the Principal investigator shall use the Clinical Investigation Medical Devices and Materials provided by Sponsor solely within and for the conduct of the clinical investigation. The Institution shall not transfer to third parties the Medical Devices for Clinical Investigation and Materials provided by Sponsor under this Agreement.

4.5

(a) *(In case of withdrawal of Medical devices by the Sponsor)*

Medical Devices for the Clinical Investigation expired or not otherwise usable, or not used at the end of the clinical investigation, will be withdrawn in full by the Sponsor (or its representative) and subsequently disposed of at its own expense.

Or,

(b) *(In case of disposal by the Institution)*

Medical devices for clinical investigation expired or not otherwise usable, or not used at the end of the clinical investigation, will be completely disposed of by the Institution, at the Sponsor's expense. The Institution undertakes to provide the Sponsor with due proof of disposal, in accordance with current legislation. For the disposal of unused Clinical Investigation Medical Devices and related operations, the Sponsor shall pay the Institution the amount indicated in Annex A (paragraph "Charges and Compensation" — Part 1) to this Agreement. This amount will be shown on the invoice with the application of VAT at the standard rate by the Institution as "a consideration ancillary to the clinical investigation for the disposal of expired or no longer used medical devices for clinical investigation".

Art. 5 — Loan for use

5.1 The Sponsor grants on loan free use to the Institution, which accepts pursuant to and for the purposes of articles 1803 and following of the Italian Civil Code, the Equipment better described below, together with the relevant material for use (hereinafter cumulatively "the Equipment") ___ (description of the asset and corresponding value in Euros). Ownership of the Equipment, as per law, is not transferred to the Institution. The effects of this loan will start from the date of delivery of the Equipment and cease at the end of the clinical investigation, when the Equipment must be returned to the Sponsor at no additional cost to the Institution.

The Parties also agree that any additional Equipment deemed necessary for conducting the study during the clinical investigation, if its characteristics and conditions are met, will be granted on loan free of charge in accordance with the discipline set out in this Agreement. The Institution and the Sponsor will proceed with a specific agreement or with an addendum/amendment to the Contract, relating to the loan, if the Equipment is provided after the conclusion of this Agreement.

5.2 *(Where applicable)* It is required that the Equipment supplied meets the following requirements:

- physical encryption of hard disks or, if not possible, predisposition of the device for remote blocking and logical encryption of files;
- installation of active-licensed antivirus;

- access to the Equipment via password authentication;
- operating system with active support for updates/patches.

The Equipment must be accompanied by a declaration of compliance with European regulations and directives. The Equipment will be subjected to acceptance testing by the technicians appointed by the Institution, in the presence of a delegate of the Sponsor, by prior agreements, for the verifications of correct installation and functionality and compliance with current legislation. At the time of delivery of the equipment supplied on loan for use by the Sponsor to the Institution, appropriate documentation is drawn up attesting the delivery.

5.3 The Sponsor assumes responsibility for the transport and installation of the Equipment and undertakes to provide, at its own expense, the technical assistance necessary for their operation as well as any consumables for their use, at no cost to the Institution.

5.4 In accordance with the provisions of the Technical Manual of the Equipment, the Sponsor will carry out, at his own expense, in collaboration with the Investigator, all the technical interventions necessary for the proper functioning of the equipment, such as quality controls, calibrations and periodic safety checks. In case of malfunction or failure of the Equipment, promptly communicated by the Investigator, the Sponsor will carry out, directly or through specialised personnel, corrective maintenance or repairing or replacement with similar equipment.

5.5 The Sponsor shall bear all charges and liability in relation to any damages that may arise to persons or property in connection with the use of the Equipment in question, if due to its defect. For this purpose, a special name plate will be affixed to any piece of Equipment indicating the property.

5.6 The Equipment will be used by the Institution's staff and/or patients and for the sole and exclusive purposes of the clinical investigation covered by this Agreement, in accordance with the provisions of the Protocol. The Institution undertakes to keep and store the Equipment in an appropriate and necessary manner, not to allocate them for use other than the one provided above, not to temporarily assign the use of the Equipment to third parties, neither free of charge nor against payment, and to return the Equipment to the Sponsor in the state in which they were delivered, except for normal deterioration as a result of use.

5.7 The Sponsor reserves the right to request the immediate return of the Equipment if used improperly or otherwise in a manner contrary to the provisions of this Agreement.

5.8 In the event of theft or loss or loss of the Equipment, the Institution will promptly provide information about the event, the submission of a formal complaint to the competent public authority, with notice of the event to the Sponsor within the same period. In all other cases of damage or destruction, the Institution shall promptly notify the Sponsor from knowledge of the event. Any fraudulent or unauthorised use must be reported immediately by the Principal investigator to the Sponsor. In the event of irreparable damage or theft of the Equipment, the Sponsor will replace it, at no additional cost to the Institution, unless the fact derives from fraud of the Institution.

5.9 It is understood that with regard to the Equipment that will be directly handled or managed by patients/parents/legal guardians (e.g. electronic diaries), the Sponsor acknowledges that the Institution is relieved of liability arising from tampering, damage or theft of the above Equipment attributable to patients/parents/legal guardians. In case of failure and/or loss by the subjects participating in the study, the Sponsor will at its own expense replace the equipment; the Institution will take charge of the delivery of the equipment to the recipient, including the

registration and delivery of the Sponsor's instructions, as well as the withdrawal at the time of departure, for any reason, of the subject from the study; the Institution will also undertake to promptly inform the Sponsor of any failure to return the equipment by the subjects participating in the study.

5.10 The authorisation to grant free use of the Equipment on loan has been granted by the Institution in accordance with its own internal procedures.

Art. 6 — Compensation

6.1 The agreed compensation, previously assessed by the Institution, per eligible patient, evaluable and having completed the experimental treatment according to the Protocol and for which the relevant CRF/eCRF has been properly compiled, including all the costs incurred by the Institution for conducting the clinical investigation and the costs of all activities related to it, is EUR ___ + VAT (*if applicable*) per patient (total EUR ___ + VAT (*if applicable*) for No. ___ patients), as better detailed in the Budget Annex A.

6 The Sponsor undertakes to pay what is due under this article on the basis of the appropriate prospectus/demonstrative statement agreed between the Parties. The payment of the above compensation will be made at the rate indicated in the Budget (Annex A, paragraph "Settlement and Invoices") on the basis of the number of patients involved in the relevant period, of the treatments carried out by them according to the protocol and in the presence of the related CRF/eCRF duly compiled and considered valid by the Sponsor based on the activities carried out.

6.3 (a) (*If the tests are carried out by a Centre outside the Institution*): The laboratory/instrumental tests, listed in Annex A (paragraph "Charges and Compensation" part 1), required by the Protocol, as approved by the Ethics Committee, will not in any way affect the Institution as carried out centrally.

Or,

6.3 (b) (*If the tests are performed at the Institution*) All laboratory/instrumental tests and any other services/additional activities not included in the agreed amount per eligible patient, required by the Sponsor, as approved by the Ethics Committee and the Competent Authority and as detailed in Annex A (paragraph "Charges and Compensation" — Part 2), will be reimbursed and invoiced by the Sponsor in addition to the agreed remuneration for "eligible" patient.

6.4 The Institution will not receive any compensation for patients not evaluable due to non-compliance with the Protocol, violation of the rules of Good Clinical Practice or non-compliance with current legislation on clinical investigations of medical devices. The Institution shall not be entitled to any compensation even for patients involved following the communication of termination and/or conclusion of the clinical investigation by the Sponsor or beyond the maximum number of subjects to be included under this Agreement, if not agreed with the Sponsor.

6.5 The Sponsor will also reimburse the Institution for all additional costs resulting from medical/diagnostic activities, including any hospitalisations, not provided for in the Protocol or subsequent amendments to the same, and not already covered by the fees listed above, if such activities are indispensable for the proper clinical management of the patient involved in the clinical investigation. Reimbursement will be made only on condition that such activities and related costs are promptly communicated, justified and documented in writing to the Sponsor and approved in writing by the Sponsor, without prejudice to the communication in encoded form of the patient's personal data.

6.6 If during the course of the clinical investigation it becomes necessary to increase the financial support to the Institution, the Sponsor may supplement this Agreement, with an addendum/amendment, providing for the appropriate increase of the budget attached herein.

6.7 In compliance with the regulations on the obligation of electronic invoicing for the supply of goods and for the provision of services even between private individuals, the Institution shall issue invoices in XML (Extensible Mark-up Language) format and transmitted through the “Sistema di interscambio” (SDI).

The Sponsor communicates the data necessary for the issuance of the electronic invoice:

COMPANY NAME ____

RECIPIENT CODE/certified email: _____

Tax Code ____

VAT number ____

INSTITUTION BANK DETAILS ____

6.8 Payments made for the services performed by the Institution (i) represent the correct market value of those services, since they are adjusted to the applicable tariff at the Institution, (ii) have been negotiated on normal commercial terms and (iii) have not been defined on the basis of the volume or value of requirements or otherwise in relation to such requirements or other economic activities that arise between the Parties. In respect of the activities carried out or the expenses incurred, including the Patients in the clinical investigation, which the Sponsor is required to pay, neither the Institution nor the Principal investigator will ask for other reimbursements or fees from other subjects.

6.9 (*where provided for by the Protocol and if the conditions provided for by law are met*): The Sponsor also makes available to patients participating in the clinical investigation the possibility to obtain coverage of the “living” expenses incurred in relation to each health service carried out at the Institution, through the procedures, ceilings and eligible expenses approved in advance by the Ethics Committee. The coverage of expenses must be carried out only and exclusively through the administration of the Institution that will implement its own procedures in this area. Each patient will submit the list of expenses to the Institution; for the purposes of the Sponsor’s coverage, this list will be duly codified by the Institution. The Institution, in view of the duration of the study, will agree on the deadlines for submission to the Sponsor of the list of expenses related to patients and submitted to the Institutions in connection with the health services performed during the reference period. The Sponsor may to check the sums requested by comparing them with the examinations performed by the patients and will make the related payments to the Institution. It will therefore be the responsibility of the Institution to cover the expenses for each patient involved, in accordance with the amounts set out in the detailed table in the Annex A - Budget below (section “Charges and Compensation” — Part 2).

If provided for in the Protocol, compensation is possible for expenses and for lost earnings directly related to participation in the clinical investigation also for the accompanying patients who are unable to travel alone such as, for example, underage patients, incapacitated subjects, fragile patients. Each patient will submit the list of expenses to the Institution or to its official delegate, for the purpose of coverage by the Sponsor.

All costs relating to items not specified in Annex A will not be reimbursed.

The Parties agree that any bank charges and fees due for foreign transfers shall be charged entirely to the payer and under no circumstances may be deducted from the amount that is credited to the beneficiary.

Art. 7 — Duration, Withdrawal and Resolution

7.1 This Agreement will be effective from the date of the last subscription (“Delivery Date”) and will be in force until the actual conclusion of the clinical investigation at the Institution, as provided for in the Study Protocol, unless otherwise agreed by the Parties. Notwithstanding the foregoing, this Agreement shall take its effect upon the granting of formal authorisation by the Competent Authority.

7.2 The Institution reserves the right to withdraw from this Agreement by written notice and with 30 days’ notice to the Sponsor by registered letter with return receipt or by certified email in the following cases:

- Sponsor’s insolvency, proposition of out-of-court agreements with the Sponsor’s creditors or initiating enforcement proceedings against the Sponsor. If the above situation concerns the person representing it, the Sponsor will be required to take over and continue the activity, if it does not require the intervention of another representative, approved by the Institution, in place of the one that has become insolvent;
- Transfer of all or part of the Sponsor’s assets to the creditors or definition with them of an agreement for the moratorium of debts.

The notice will take effect as soon as the Sponsor receives the above communication.

7.3 The Sponsor, pursuant to Art. 1373, paragraph 2 of the Italian Civil Code, reserves the right to withdraw from this Agreement at any time for justified reasons by written communication sent by registered letter with return receipt or by certified email, with 30 days’ notice. Such notice shall take effect as soon as the Institution receives such notice.

In case of withdrawal of the Sponsor, the obligations assumed and the expenses incurred by the Institution on the date of the withdrawal communication are in any case without prejudice. In particular, the Sponsor will pay to the Institution all the documented and non-revocable expenses incurred in order to ensure the correct and effective conduct of the clinical investigation, (where applicable, including expenses incurred by the Institution towards patients-participants), as well as the remuneration accrued up to that time.

In case of early withdrawal, the Sponsor has the right to receive, as original owner, all data and results, even partial, obtained by the Institution during the clinical investigation and also subsequently, if derived from or related to it.

7.4 The interruption of the investigation may take place pursuant to Art. 76 and 77 of the Regulation in any time with immediate effect, pursuant to the provisions of paragraph 5 of Art. 2, if there is valid and documented reason to believe that the continuation of the clinical investigation may represent an unacceptable risk to the safety and health of patients. In the event of termination of the clinical investigation, the Sponsor will pay to the Institution the reimbursements of the expenses and the remuneration actually accrued and documented up to that time.

7.5 Furthermore, it is understood that the early termination of the Agreement will not result in any right of one Party to make any other claims for compensation or requests for payment further than what is agreed.

7.6 The effects of this Agreement shall automatically cease pursuant to Art. 1454 of the Italian Civil Code in the event that one of the Parties has failed to fulfil any of the obligations provided for in this Agreement within 30 days of the written request for fulfilment made by the other party. In any case, it remains without prejudice to the applicability of Art. 1218 et seq. of the Italian Civil Code.

7.7 In the event of termination of this Agreement not resulting from failure by the Institution, this shall be entitled to reimbursement of the expenses actually incurred for the clinical investigation prior to receipt of the termination notice and to a fee for the services rendered in accordance with the Protocol and this Agreement, in proportion to the activity carried out until the termination. The Institution undertakes to return to the Sponsor any amounts already cleared and related to activities not carried out.

7.8 In all cases of interruption or termination of this Agreement, all precautions will be implemented to ensure the maximum protection of patients already involved, in accordance with the provisions of the protocol approved by the Ethics Committee.

Art. 8 — Insurance coverage

8.1 The Sponsor is required to guarantee, in accordance with current legislation, compensation for the damages suffered by patients and attributable to participation in the clinical investigation, proportionate to the nature and extent of the resulting risks.

8.2 Without prejudice to the provisions of Art. 69 of Regulation 2017/745 and Law No. 24 of 8 March 2017, and to the respective implementing measures, the insurance coverage provided by the Sponsor guarantees against the assumptions of civil liability of the Sponsor, of the health institution where the Clinical Investigation is performed, the Principal investigator, and the other investigators involved at the Institution's Centre.

8.3 (*where applicable*) The Sponsor declares, by signing this Agreement, that it has taken out adequate insurance policy (No. ____, with the Company ____) for third party civil liability, to cover the risk of any damage caused to patients, users and healthcare professionals for participation in the clinical investigation pursuant to Art. 69 of Regulation 2017/745. The Ethics Committee has considered that insurance policy complies with the terms of the law and adequately protects the subjects involved in the clinical investigation.

8.4 By signing this Agreement, the Sponsor declares to bear the consequences related to any inadequacies, even arising, of the insurance coverage in question, supplementing them where necessary in accordance with the provisions of Art. 8.1.

8.5 In particular, the Sponsor, in the event that it intends to withdraw from the Agreement, guarantees that the Insurance company ensures in any case the coverage of the subjects already included in the clinical study also for the continuation of the clinical investigation.

8.6 At the time of the accident, the Institution is required to communicate the existence of insurance coverage for Third Party Medical Malpractice liability (to cover both the Institution and the medical personnel who used the device), pursuant to Art. 1910 of the Italian Civil Code.

Art. 9 — Final report, ownership and use of results

9.1 The Sponsor undertakes to disclose all results of the study even if negative.

9.2 The Sponsor takes responsibility for the preparation of the final clinical report and for sending the summary of the results of the clinical investigation, within the deadlines provided for by the current legislation, to the Principal investigator and to the Ethics Committee.

9.3 All data, results, information, materials, discoveries and inventions resulting from performing the clinical investigation, in the pursuit of its objectives, shall be the exclusive property of the Sponsor, without prejudice to the right of the investigators to be recognised as authors.

In the face of a procedure initiated by the Sponsor for filing a patent application concerning inventions obtained during the clinical investigation, the Institution and the Principal investigator undertake to provide the Sponsor with the support, also documentary, useful for this purpose.

9.4 The Institution may use the data and results of the clinical investigation, of which it is an independent data controller in accordance with the law, solely for its own internal, scientific and research purposes, which are not commercial in nature. Such use shall under no circumstances affect the confidentiality of the same and the patent protection of the related intellectual property rights of the Sponsor.

The Parties shall mutually recognise that they will retain industrial and intellectual property rights relating to their previous knowledge (background knowledge) and knowledge developed or obtained in the course of the clinical investigation, but irrespective of its conduct and objectives (sideground knowledge).

9.5 The provisions of this article shall remain valid and effective even after termination of the effects of this Agreement.

Art. 10 — Confidentiality of technical and commercial information and dissemination of results

10.1 By signing this Agreement, the Institution undertakes to keep confidential for the entire duration of this Agreement (deadline extensible in negotiation *until they fall into the public domain, if necessary under any agreement with licensors*), all technical and/or commercial information made available to it by the Sponsor and/or developed during the clinical investigation and in pursuit of the objectives of the same, classifiable as “Commercial Secrets” pursuant to Articles 98 and 99 of the Industrial Property Code (Legislative Decree 30/2005, as amended by Legislative Decree 63/2018 in transposition of EU Directive 2016/943), adopting any measures (contractual, technological or physical) suitable for their protection, including against its employees, collaborators, sub-contractors, assignors or assignees.

Each Party shall also declare and warrant the following:

(I) its Commercial Secrets have been lawfully acquired, used and disclosed, and -as far as it is known- there are no legal proceedings, disputes, claims for compensation or compensation even out of court, by third parties claiming ownership of such secrets.

(II) it will, therefore, hold the other Party harmless and will indemnify the other Party from legal proceedings, disputes, claims or claims for compensation, including out-of-court claims, by third parties claiming ownership of such secrets.

10.2 The Parties are obliged to properly disseminate and publish the results of the clinical investigation and to adequately communicate them to the participating patients and to the patients’ representatives. The Sponsor, in accordance with current legislation, is required to make public promptly, as soon as available by all the Participating Centres, and in any case no later than the deadlines established for that purpose by the applicable provisions of the European Union.

10.3 Pursuant to Art. 5(2), letter c) of the Ministerial Decree of 8 February 2013, the Principal investigator has the right to disseminate and publish, without limitation, the results of the clinical investigation obtained at the Institution, in compliance with the provisions in force regarding the confidentiality of sensitive data, the protection of personal data and the protection of intellectual property, as well as in compliance with the terms and conditions set out in this Agreement.

In order to ensure the correctness of the collection and the truthfulness of the processing of the data and the results of the Investigation obtained at the Institution, the Principal investigator must forward to the Sponsor the text of the document intended to be presented or published. Should issues arise concerning the scientific integrity of the document and/or relating to regulatory, patent or intellectual property protection, the Parties shall review the document within 60 days. The Principal Investigator will agree to take into account the Sponsor's suggestions in the publication or presentation only if necessary for the protection of the confidentiality of information and personal data and the protection of intellectual property, provided that they do not conflict with the reliability of the data, the rights, safety and well-being of patients.

10.4 The Sponsor acknowledges that it has no right to request the deletion of the information contained in the document, except where such requests and changes are necessary for the protection of data confidentiality, the protection of personal data and the protection of intellectual property.

10.5 In order to submit a patent application and if it is necessary, the Sponsor may request the Principal investigator to defer the publication or presentation of the document for a further 90 days.

In the case of a multicentre clinical investigation, the Principal investigator shall not publish the data of his Centre until all the results of the clinical investigation have been fully published or for at least 12 months from the end of the clinical investigation, its interruption or early closure.

If the Sponsor, or a third party appointed by the Sponsor does not publish the results of a multicentre clinical investigation within ___ months (*in accordance with current legislation at least twelve months*) from the end of the multicentre clinical investigation, the Investigator may publish the results obtained at the Institution, in compliance with the provisions of this article.

Art. 11 — Protection of personal data

11.1 The Parties, in performing the activities provided for in this Agreement, undertake to process personal data, of which they become aware for any reason during the clinical investigation, in compliance with the objectives set out in the previous articles and in accordance with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, and pursuant to the related national laws and administrative provisions in force, with any subsequent amendments and/or additions thereto (hereinafter, collectively, "Data Protection Laws"), and to any regulations of the Institutions.

11.2 The terms used in this article, in the Agreement, in the information and consent documentation and in any other document used for the purposes of the clinical investigation shall be understood and used in accordance with the meaning attributed to them in Annex B.

11.3 The Institution and the Sponsor qualify as independent data controllers pursuant to Art. 4 (paragraph 17) of the GDPR. Each Party shall provide at its own expenses, as part of its organisational structure, any appointments of Data Processors and attribution of functions and tasks to designated subjects, who operate under their authority, in accordance with the GDPR and current legislation.

11.4 For the purposes of the clinical investigation, personal data will be processed relating to the following categories of data subjects: subjects participating in the clinical investigation; persons working for the Parties. These data subjects are informed about the processing that concerns them by means of appropriate information. For the purposes of the clinical investigation, the following types of personal data will be processed: data pursuant to Art. 4 No. 1 of the GDPR; data falling under the “special” categories of personal data - and in particular data relating to health and sex life, genetic data - pursuant to Art. 9 of the GDPR. These data will be processed in compliance with the principles of lawfulness, correctness, transparency, adequacy, relevance and necessity referred to in Art.5, paragraph 1 of the GDPR.

11.5 The Sponsor may transmit the data to affiliates of the Sponsor group and to third parties operating on its behalf, even abroad, in countries outside the European Union only in compliance with the conditions set out in Articles 44 et seq. of the GDPR. In this case the Sponsor will ensure an adequate level of protection of personal data also through the use of the Standard Contractual Clauses approved by the European Commission. If the Sponsor is established in a State which does not fall within the scope of European Union law and if the European Commission has decided that such country does not guarantee an adequate level of protection pursuant to Articles 44 and 45 of the EU GDPR 2016/679, the Sponsor and the Institution shall complete and sign the Standard Contractual Clauses document (not attached to this Agreement).

11.6 The Parties shall ensure that persons authorised by them to process personal data for the purposes of the clinical investigation comply with the principles set out to protect the right to protection of personal data and the right to confidentiality, and that persons who have access to personal data are obliged to process them in accordance with the instructions laid down, in accordance with this Article, by the relevant data controller.

11.7 The Principal Investigator is identified by the Institution as a person authorised to process data in accordance with Art. 29 of the GDPR and as an appointed subject pursuant to Art. 2 m of the Code.

11.8 The Principal Investigator must inform each patient in a clear and complete manner, before the start of the Clinical Investigation (including its prodromal and screening phases) about the nature, purpose, results, consequences, risks and modalities of the processing of personal data; in particular, the patient must also be informed that national and foreign authorities, as well as the Ethics Committee, may access, in the context of monitoring, verification and control on research, the documentation relating to the clinical investigation as well as the original health documentation of the patient, and that they may also exceed in vision, within the scope of their respective competences, Monitors and Auditors.

11.9 The Principal Investigator must obtain from the duly informed patient the consent document to both the participation in the clinical investigation, and data processing. The Institution is responsible for retention of this document.

11.10 If one party finds a breach of personal data, it undertakes to communicate it to the other within 48 hours from the verification of the violation, without prejudice to its autonomy in assessing the existence of the conditions and in the fulfilment of the obligations provided for by Articles 33 and 34 of the GDPR.

Art. 12 — Amendments

12.1 This Agreement and its annexes/addenda, together with the Protocol as an integral part, constitute the entire agreement between the Parties.

12.2 The Agreement may be amended only with the written consent of both Parties. Any changes will be the subject of an addendum to this Agreement and will run from the date of their subscription, unless otherwise agreed between the Parties.

Art. 13 — Anti-corruption rules

13.1 The Institution and the Sponsor undertake to comply with the anti-corruption regulations applicable in Italy.

13.2 The Sponsor declares to have adopted supervisory and control measures in order to comply with and implement the provisions of Legislative Decree No. 231 of 8 June 2001 as well as, as applicable and not contrary to the legislation in force in Italy, the principles of the Foreign Corrupt Practices Act of the United States, as amended. The Institution and its clinical and administrative structures undertake to collaborate in good faith, within the limits of the Italian legislation referred to above, with the staff and management of the Sponsor in order to facilitate the full and correct implementation of the obligations resulting from it and the implementation of the operational procedures developed for this purpose by the Sponsor.

13.3 Pursuant to and for the purposes of Law No. 190 of 06 November 2012 (“Anti-Corruption Law”) and its subsequent amendments, the Institution declares to have adopted the Three-year Plan for the Prevention of Corruption.

(Where applicable and not in conflict with current legislation) The Sponsor declares to have adopted its Code of Ethics, which can be found on the web page () *(insert link to the website)*

13.4. The Institution and the Sponsor undertake to immediately inform the other party of any violation of this article of which it becomes aware and to make available all information and documentation for any appropriate verification.

13.5 The Sponsor may disclose for any legitimate purpose, within the limits of data processing legislation, the terms of this Agreement or any amendment thereto.

13.6 Infringement of the provisions of this Article constitutes a serious breach of this Agreement pursuant to and for the purposes of Art. 1456 of the Italian Civil Code, thus affecting the relationship of trust between the Parties.

Art. 14 — Transfer of rights, transfer of the Agreement

14.1 This Agreement is of a fiduciary nature and, therefore, the Parties may not assign or transfer the same to third parties, without prior written consent of the other Party.

Each Party agrees that the other Party may assign and/or transfer in whole or in part the rights and obligations arising directly or indirectly from the signing of this Agreement to a successor or to a company or entity associated with it, upon acceptance by the assignee of all the terms and conditions of this Agreement. Any transfer of rights in the absence of the above conditions will be considered null and void.

14.2 In the event of a change of name of Institution, no amendment to this Agreement will be necessary. However, the Institution shall promptly notify the Sponsor of such change of name.

Art. 15 — Tax charges

15.1 This Agreement is signed digitally in accordance with current legislation. The taxes and duties must be paid which are inherent and consequent to the conclusion of this Agreement, including the stamp duty on the electronic original referred to in Art. 2 of Annex Table A — Tariff Part I of Presidential Decree 642/1972 and the registration tax, in compliance with the applicable legislation.

Art. 16 — Regulatory Law and Jurisdiction

(for the determination of the regulatory law and Jurisdiction, please refer to Circular No. 5 of the Coordination Centre, available at the link

<https://www.aifa.gov.it/centro-coordinamento-comitati-etici>, section “Circulars”)

16.1

(a) generally and in any case if the Parties are both Italian): The law applicable to this Agreement is that of the Italian State.

Or,

(b) (in the case of multi-centre international studies, if the parties have different nationalities and the Italian law is not chosen, but e.g. the law uniformly applied by the Sponsor for all participating centres, wherever located): The governing law of this Agreement is the law....., without prejudice to the norms of the necessary application of the Italian law, in particular with regard to the protection of patients’ rights.

16.2 For any disputes that may arise in relation to the interpretation, application and execution of this Agreement, without prejudice to the commitment of the Parties to make a prior attempt to conciliate in extrajudicial proceedings, the Court of the registered office of the.... will have exclusive jurisdiction.

Art. 17 — Language

17.1 In the event of any discrepancy between the English and Italian versions of this Agreement, the Italian version shall prevail.

___, (date) __/__/__

For the Sponsor

The Legal Representative or his/her delegate

Mr/Ms _____

Signature _____

___, (date) __/__/__

For the Institution

The Legal Representative or his/her delegate

Mr/Ms _____

Signature _____

The parties agree to each other for mutual clarity, that this Agreement, drawn up on the basis of the minimum contents identified pursuant to Art. 2 paragraph 6 of Law No. 3 of 11 January 2018, is to be considered known and accepted in all its parts and that therefore the provisions do not apply of Articles 1341 and 1342 of the Italian Civil Code.

____, (date) __/__/____

For the Sponsor

The Legal Representative or his/her delegate

Mr/Ms _____

Signature _____

For the Institution

The Legal Representative and his/her delegate

Mr/Ms _____

Signature _____

ANNEX A — BUDGET

CHARGES AND COMPENSATION

Part 1 — Fixed Charges and Compensation per Patient Involved in the Clinical Investigation

For example, include the following items:

- Supply of the Investigational Medical Device and/or any other material under investigation or necessary to carry out the same so that there is no increase in costs borne by the NHS (diagnostic kits, medical devices, etc.)
- Gross compensation per patient involved in the study: EUR ___+ VAT (*provide multiple compensations for studies with different remuneration for each protocol arm*)
- Compensation for the Trial centre per completed Patient (Compensation per patient involved — corporate overhead — all costs incurred by the Institution for the Clinical Investigation¹): EUR ___ + VAT
- Intermediate economic phases (in case patients do not complete the investigational process): Exam Compensation/patient (Exam no ___ EUR ___ + VAT;.; Contacts EUR_____ + VAT; Exam no_ EUR_____ + VAT)
- (*paragraph to be inserted only if there are no additional costs referred to in Part 2*). All reimbursable costs related to the study, including those covered by the contribution per patient involved in the study, will not result in increased costs to the NHS (e.g. there are no additional services, instrumental and laboratory examinations are routine for patients in the study, or instrumental examinations are routine for patients in the study and laboratory examinations will be carried out with diagnostic kits provided by ___ or laboratory examinations will be carried out in a centralised external laboratory at the expense of the Sponsor).

Part 2 — Additional costs for instrumental and/or laboratory examinations to be carried out on the basis of the Institution’s tariffs (or on the basis of the tariff nomenclature of the Region where the Trial Centre is located) in force at the time of the provision of the respective services

-

- TARIFF CODE	- DESCRIPTION OF EXAMINATION	- No. SERVICES per patient	- AMOUNT EUR___+ VAT
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-
-	-	-	-

Part 3 Compensation for patients/carers involved in the clinical study: (if applicable)

Reference is made to the provisions of current legislation, implementing Regulation (EU) 745/2017.

¹ • general administrative costs, costs incurred for the management of the MD(s) covered by the Clinical Investigation

Settlement and Invoices

- The compensation must be paid within ____ days (*indicate*) from receipt of the invoice.
- The invoice must be issued on a scheduled basis ____ (quarterly/semesterly/annually or progressive targets) as matured during the reference period, based on a specific request for invoice issuance by the Sponsor.

ANNEX B — GLOSSARY ON THE PROTECTION OF PERSONAL DATA

(Terminology related to the GDPR — Reg. EU n. 2016/679 — and the Italian implementing rules)

- **Personal data** — any information concerning an identified or identifiable natural person (“data subject”); an identifiable natural person is a natural person who can be identified, directly or indirectly, with particular reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more elements characteristic of his/her physical, physiological, genetic, mental, economic, cultural or social identity;
- **Data processing** — any operation or set of operations, carried out with or without the aid of automated processes and applied to personal data or sets of personal data, such as collection, recording, organisation, structuring, storage, adaptation or modification, retrieval, consultation, use, disclosure by transmission, dissemination or any other form of making available, comparison or interconnection, restriction, deletion or destruction;
- **Pseudonymisation** — processing of personal data such that the data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is stored separately and subject to technical and organisational measures to ensure that such personal data are not attributed to an identified or identifiable natural person;
- **Data subject** — the natural person to whom the personal data refer (Art. 4 No. 1 GDPR);
- **Data controller** — the natural or legal person, public authority, service or other body which, individually or together with others, determines the purposes and means of personal data processing; where the purposes and means of such processing are determined by EU or Member State law, the controller or the specific criteria applicable to his/her designation may be established by EU or Member State law;
- **Other subjects processing personal data** — the persons authorised to process personal data under the direct authority of the Data Controller or the Data Processor (Articles 28(3)(b), 29 and 32, No. 4 GDPR), including therefore natural persons to whom the Data Controller or the Data Processor have assigned specific tasks and functions related to the processing, who operate under the authority of the Data Controller and within the framework of the organisational structure, pursuant to Art. 2 *quaterdecies* of Legislative Decree 196/2003 as amended by Legislative Decree 101/2018;
- **Data processor** — the natural or legal person, public authority, service or other body that processes personal data on behalf of the data controller;
- **Consent of the data subject** — any freely expressed, specific, informed and unambiguous will of the data subject, whereby the data subject expresses his or her consent, by means of an unequivocal declaration or positive action, that the personal data concerning him or her are being processed;
- **Personal data breach** — a security breach involving accidentally or unlawfully the destruction, loss, modification, unauthorised disclosure or access to personal data transmitted, stored or otherwise processed;
- **Health-related data** — personal data relating to a natural person’s physical or mental health, including the provision of health care services, revealing information about his or her health status;
- **Genetic data** — personal data relating to inherited or acquired genetic characteristics of a natural person providing unique information on the physiology or health of that natural

person and resulting in particular from the analysis of a biological sample of the natural person concerned;

- **Biological sample** — any sample of biological material from which genetic data characteristic of an individual can be extracted;
- **Sponsor** — the person, company, institution or body that assumes responsibility to initiate, manage and/or finance a clinical investigation;
- **CRO** — contract research organisation to which the sponsor may entrust part or all of its expertise in clinical investigation;
- **Monitor** — the person responsible for monitoring the clinical investigation identified by Sponsor/CRO;
- **Auditor** — the person responsible for carrying out the verification on the conduct of the clinical investigation, as an integral part of quality assurance, identified by the Sponsor/CRO.