AGREEMENT FOR CLINICAL INVESTIGATION
ON THE MEDICAL DEVICE WITHOUT CE MARKING OR NOT MARKED FOR THE USE FOR WHICH IT IS INTENDED [Name of medical device]
CLINICAL INVESTIGATION "_____"

BETWEEN:

_____ (*insert name of Healthcare Facility*) (hereinafter the "Entity"), headquartered in _____ tax code and VAT no. _____, through its Legal Representative, _____, in the capacity of _____ (*indicate whether Director General CEO, Extraordinary Commissioner, etc*.), who has granted _____ (*position of signatory*) (hereinafter "_____") with the powers to enter into this Agreement

AND

(a) _____ (*insert the Sponsor according to legislation in force*) headquartered in _____ , tax code and VAT no. _____, through its Legal Representative _____, in the capacity of _____, (hereinafter the "Sponsor")

(For international Clinical investigations and contracts made by the local branch of a multinational pharmaceutical company)
_____ (*insert name of Company*), headquartered in _____ tax code _____ and VAT no. _____, through its Legal Representative _____, in the capacity of _____ (hereinafter the "Company"), which by virtue of the authority/mandate dated _____ is acting in the name and on behalf of/in its own name and on behalf of the Clinical investigation Sponsor, _____, headquartered in _____, VAT no. _____ (hereinafter the "Sponsor")'

Or

(b) (If mandate given to the CRO)
_____(*insert the name of the Contract Research Organization - CRO*), headquartered in _____,tax code _____ and VAT no. _____, through its Legal Representative, _____ in the capacity of _____ (hereinafter the "CRO"), acting in the name and on behalf of/in its own name and on behalf of/in the interests of _____ (hereinafter the "Sponsor"), by virtue of the authority/mandate/power of attorney granted on _____.

hereinafter individually/collectively "the Party/the Parties"

Whereas:

- it is in the interest of the Sponsor to perform the Clinical investigation on a medical device entitled: "_____" (hereinafter "Clinical investigation"), relating to the Protocol version no. _____ dated _____ as amended, duly approved (hereinafter the "Protocol"), code no. _____, at _____ the Entity, under the responsibility of Dr./Prof. _____, as the Scientific Director of the Clinical investigation covered by this Agreement (hereinafter the "Principal Investigator"), at _____ (*insert name of Unit/Department, etc.*) (hereinafter the "Clinical Investigation Centre");

- the Sponsor/CRO has appointed Dr./Prof. _____ as the scientific and technical contact for the part under its responsibility. The Sponsor may change the scientific and technical contact by giving written notice to the Entity;

- the Investigation Centre has the technical and scientific know-how to carry out the Clinical investigation and is a suitable facility for the Clinical investigation to be conducted in accordance with the applicable regulations;

- the Investigator and the healthcare staff playing any part in the Clinical investigation under the supervision of the Investigator (hereinafter the "Co-investigators") are qualified to conduct the Clinical investigation in accordance with the applicable regulations, are familiar with the Protocol and the standards of good clinical practice and possess the necessary regulatory and legal requirements, including compliance with current legislation regarding the conflict of interests;
- except where agreed otherwise in writing by the Parties, the Entity shall only conduct the Clinical investigation on its own facilities;

(a) *(If no equipment loan is necessary)*

- the Entity has the equipment necessary to execute the Clinical investigation in accordance with the Protocol;

Or

(b) (*if an equipment loan is necessary)*

- although the Entity does have equipment suitable to execute the Clinical investigation, it will receive, on free loan from the Sponsor in accordance with the Italian Civil Code, the equipment and/or goods that are essential for the successful outcome of the Clinical investigation, as listed in Article 5 of this Agreement;

(a) (*In the event in which the device is free from CE marking and belonging to classes, 1, 2a or 2b excluding long-term implantable and invasive devices*)

- The Sponsor/CRO presented to the Ministry of Health (hereinafter the "Competent Authority") the request for authorisation to perform the Clinical investigation on the device free from CE marking on _____ and on _____ the Ministry authorised the trial;

Or (in the event in which the 60 days from the authorisation request to the Ministry of Health have not yet passed)

- The Sponsor/CRO presented to the Ministry of Health the request for authorisation to perform the Clinical investigation on the device free from CE marking on _____;

(b) (*In the case in which the device is free from CE marking and belonging to class 3, or is a long-term implantable and invasive device belonging to classes 2a and 2b*)

- The Sponsor/CRO received from the Ministry of Health the authorisation to perform the Clinical investigation with a note written on _____;

Or (if 60 days have passed without the authorisation being received)

- The Sponsor/CRO presented to the Ministry of Health the request for authorisation to perform the Clinical investigation on the device on _____ and the Ministry did not respond by the 60-day expiry date, thus authorising the performance of the trial through tacit consent:
- on _____ the competent Ethics Committee expressed a favourable view for the performance of the Clinical Investigation;
- the Sponsor has taken out an insurance policy as better specified by Article 8 of this Agreement in accordance with Article 3 letter n of Italian Ministerial Decree of 2/8/2005.

Now therefore, in consideration of the foregoing, it is hereby agreed as follows:

Art. 1 – Recitals

1.1 The recitals, the Protocol – even if not physically attached – and all the annexes including the budget (Annex A) and the data protection glossary (Annex B) form an integral and substantial part of this Agreement.

Art. 2 – Subject of the agreement

2.1 The Sponsor/CRO hereby entrusts the Entity with the execution of the Clinical investigation under the terms of this Agreement, in accordance with the Protocol and any subsequent amendments, and with the amendments to this Agreement/budget resulting from such amendments formalised by the necessary deeds of amendment, duly signed.

2.2 The Clinical investigation is to be conducted in strict compliance with the Protocol, in the version in force as accepted by the Principal Investigator and approved by the Ethics Committee and the Competent Authority, in conformity with the laws applicable to Clinical investigations on medical devices and the principles of ethics and medical practice followed by the healthcare staff involved in the investigation in any capacity.

2.3 The Clinical investigation shall also be conducted in accordance with the principles of the Convention on Human Rights and Biomedicine, the updated version of the Helsinki Declaration, the current rules of good clinical practice, and in accordance with the applicable laws on transparency, anti-corruption and the current data protection regulations.

2.4 By signing this Agreement, the Parties declare that they know and accept the contents of the above rules and regulations.

2.5 The Sponsor and the Principal Investigator have an obligation to protect patients' safety and, where required in the circumstances, may take urgent, appropriate measures to protect patients' safety such as temporarily suspending the trial (interruption of treatment for patients already enrolled in the Clinical investigation or interruption of the enrolment of new patients), even without the necessary approval of the Ethics Committee and, if applicable, the Competent Authority, subject to the Sponsor's obligation to inform the Ethics Committee and the Competent Authority immediately of any new events, the measures taken, and the programme of measures to be taken in the future, and will duly complete the procedures required by the applicable laws.

2.6

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

The (Entity) envisages including indicatively . ____ patients by _____ *(insert the estimated date).* The Parties acknowledge that any increase in the number of patients to be enrolled at the Entity's investigation centre must be agreed in writing in advance between the Parties, and sent to the Ethics Committee and, if applicable, to the Competent Authority as a substantial amendment. Any increase in the caseload made in accordance with the above conditions does not require the stipulation of an addendum to this Agreement if the financial conditions per patient, as agreed herein, apply to all the additional patients.

Or

(b) In the case of a multi-centre competitive-enrolment Clinical investigation
As the Clinical Investigation involves the competitive enrolment of patients, the Entity expects to include approximately _____ patients, with a global maximum of _____ patients eligible for the Clinical investigation, and limited to the terms provided for by the Sponsor.
The enrolment period may be changed depending on the national or international trend in enrolment. When the total number of patients permitted for the entire Clinical investigation has been reached, the inclusion of further patients will be closed automatically, regardless of the number of patients enrolled at the Entity, apart from patients who have already provided their consent to take part in the investigation, unless the patients themselves withdraw their consent. The Sponsor will notify the Entity accordingly.

2.7 The Entity and the Sponsor will keep the Clinical investigation documentation (the "*trial master file"*) for the period of time specified in the applicable laws. The Entity undertakes, at the date of this provision, to conserve the documentation for a period of ____ years. The Sponsor is obligated to inform the Investigation Centre of the expiry of the mandatory conservation period (*only if requested*). At the request of the Sponsor, after expiry of the mandatory conservation period, the Parties may agree the terms of a further conservation period.

2.8 The Entity and the Sponsor, each within their own sphere of responsibility, shall also use forms of digitalisation (or dematerialisation) to conserve the documentation. Regardless of whether or not the archived Clinical Investigation documentation contains personal data (of a special nature or otherwise), according to the definitions in Regulation (EU) No. 679/2016, the Entity and the Sponsor shall take all the physical and technical measures referred to in Article 32 of said Regulation (EU) No. 679/2016 and shall carry out any security checks as required by ISO 27001 as amended to protect the data, information and documents (both printed and digital). The archiving system shall guarantee not only the integrity of the data, information and printed/digital documents but also their future legibility throughout the mandatory conservation period. To fulfil such obligation both the Sponsor and the Entity may rely on external service providers to manage the archiving obligation.

2.9 The Sponsor, the Entity and the Principal Investigator shall comply with the directions, indications, instructions and recommendations given by the Ethics Committee and by the Competent Authority.

Art. 3 - Principal Investigator and Co-investigators

3.1 The Principal Investigator shall be supported in the execution of the Clinical investigation by the healthcare and non-healthcare personnel and by any contractors engaged by the Entity, as appointed by the Entity and operating under its responsibility for all aspects pertaining to this Clinical investigation, who are qualified to conduct the Clinical investigation, and who have

previously received adequate training as provided for in the applicable laws, by the Sponsor/CRO and who have declared their willingness to take part in the Clinical investigation (the Co-investigators). Without affecting the foregoing, the definition of "Investigators" does not include any medical or non-medical personnel who perform proprietary institutional activities in the context of the Clinical investigation (for example pharmacists, IT technicians).

3.2 The Parties acknowledge that the Principal Investigator is bound by all the responsibilities and obligations imposed on their role by the applicable regulations on Clinical investigations on medical devices.

3.3 This Agreement is made between the Sponsor/CRO and the Entity. The Sponsor/CRO is extraneous to the relations between the Entity, the Principal Investigator and the Co-investigators, and is thus indemnified in respect of any claim that the personnel of the Entity involved in the trial may make in relation to the Clinical investigation.

3.4 In relation to the Clinical investigation, the Principal Investigator and the Co-investigators may not receive any direct or indirect compensation from the Sponsor/CRO, nor have any contact or dealings with the Sponsor/CRO or relations of any kind that are not of a technical or scientific nature.

3.5 If the relationship between the Principal Investigator and the Entity ends for any reason, the Entity will inform the Sponsor/CRO in writing and indicate the name of a replacement. The named replacement must be approved by the Sponsor/CRO and by the competent Ethics Committee. The Entity guarantees that the new Principal Investigator is qualified to continue the Trial, that they will accept the terms and conditions of this Agreement and that they will agree to respect the Protocol when executing the Clinical investigation. Pending approval of the substantial amendment for the change of Principal Investigator, the investigator indicated by the Sponsor shall carry out the necessary trial activities. If the Sponsor does not intend to accept the name of the replacement proposed by the Entity, or if the Entity does not propose a substitute, the Sponsor/CRO may terminate this Agreement in accordance with the provisions of Article 7.

3.6 Before starting the Clinical investigation, the Principal Investigator shall obtain the informed consent of the patient or his/her legal representative in accordance with the current laws on Clinical investigations, and also in accordance with Regulation (EU) No. 2016/679 and the Italian enacting laws (legislative decree 196 of 30 June 2003 as amended by legislative decree 101 dated 10 August 2018).

Consent shall also be provided for the processing of personal data in accordance with the current Italian and EC laws on data protection as amended, and as outlined in Article 11 below.

3.7 The Principal Investigator shall provide information to the Sponsor/CRO and to the Ethics Committee in relation to the progress of the Clinical investigation and shall promptly inform the Sponsor/CRO of any serious adverse events, subject to any other obligations to report to the Ethics Committee in accordance with current regulations, plus any other clinical information that is relevant to the trial and indicated in the Protocol (e.g: pregnancy) that is directly or indirectly related to the execution of the Clinical investigation, in accordance with the provisions of the Protocol, the rules of Good Clinical Practice and the laws applicable to pharmacovigilance and Clinical investigations on medical devices and, where applicable, on pharmacovigilance.

3.8 The Entity guarantees that the Principal Investigator shall undertake to execute the Clinical investigation in accordance with the highest standards of diligence.

3.8.1 The Principal Investigator shall keep all of the Case Report Forms (CRF), duly compiled, in accordance with the terms and conditions of the Protocol for the Clinical investigation and with

the applicable regulations, in printed or digital form, and in any case they shall be delivered promptly in accordance with the GCP, by the date indicated in the Clinical investigation Protocol.

3.8.2 The Principal Investigator shall also resolve any queries raised by the Sponsor/CRO by the date indicated in the Clinical investigation Protocol.

3.8.3 To verify the correspondence between the data recorded on the CRF and the data contained in the original clinical records (e.g. clinical file), the Entity and the Principal Investigator shall allow direct access to the source data during the monitoring visits and any audits by the Sponsor/CRO and inspections by the Competent Authorities, including remote methods, provided that the laws on confidentiality and patient data protection are respected.

3.8.4 The Entity and the Principal Investigator, having been informed sufficiently in advance, shall allow the correct execution of the monitoring and auditing at the Clinical investigation Centre _____ by the Sponsor/CRO and by the Competent Authority, such activities to be carried out to guarantee the proper execution of the Clinical investigation.

3.9 (*Where appropriate, taking into account the current regulations on data protection)* after receipt of the favourable opinion of the competent facility, the software _____ will be provided free of charge (indicate name of software).

3.9.1 With regard to the network infrastructure and information systems, the Sponsor shall agree the procedure for the installation and delivery of the product, after the competent local centre has issued a positive report on feasibility and technical compatibility with the standards in place at the Entity, and on medium-term sustainability with the existing services.

3.9.2 In the same way, the Sponsor undertakes to de-install the product on completion of the trial, at no cost to the Entity.

3.9.3 The Sponsor warrants that the Entity's use of the products indicated above, in the context of the trial, shall not create any obligation for the Entity to purchase or subscribe to the Sponsor's supplies or services, that it does not infringe any third party licences or rights and that it does not bind the Entity to use the product beyond the date provided for in the Trial.

3.9.4 The Sponsor further warrants that the use of the product in the context of the trial shall not entail, for the Entity, any costs relating to the servicing, modification or upgrading of any of the hardware/software components in its IT network and therefore, it shall not lead to any breach by the Entity of its contractual obligations towards its direct suppliers.

3.9.5 In any event the Sponsor shall indemnify the Entity respect of any direct or indirect losses deriving from use of the product in accordance with the instructions of the manufacturer/supplier.

3.10 The Entity shall promptly inform the Sponsor if a regulatory authority informs the Entity of an inspection or audit in relation to the Clinical investigation and, unless expressly refused by the Competent Authority, the Entity will authorise the Sponsor to take part, while sending the Sponsor all the written communications received and/or transmitted for the purposes of the audit or inspection.

3.11 These activities must in no way prejudice the ordinary institutional activities of the Entity.

3.12 The Entity or the Sponsor guarantees that the biological samples (blood, urine, saliva, etc.) that may be collected from patients undergoing the Clinical investigation shall only be used for the purposes of the Clinical investigation in accordance with the provisions of the Protocol and of the current regulations. Any conservation and subsequent use are subject to the acquisition of specific informed consent from the patient (or the parent/legal guardian), to the favourable opinion of the Ethics Committee in accordance with the limits and guarantees provided for in the current regulations and guidelines referred to in Article 1 of Italian Legislative Decree no. 52 of 14 May 2018.

Art. 4 – Medical devices for the Clinical investigation and Materials

4.1 The Sponsor undertakes to supply to the Entity free of charge, for the entire duration of the Clinical investigation and in the amounts necessary and sufficient for the performance of the Clinical investigation, the Medical devices investigated by the Clinical investigation (_____) (hereinafter "Medical devices for the Clinical investigation"), in class……, and to supply any other material necessary for performing the Clinical investigation (hereinafter “Materials”). In the event of Clinical investigations performed with medical devices bearing CE marking, the extra costs with respect to normal clinical practice, deriving from the application of this paragraph, are to be covered by the manufacturer. The medical devices necessary for these Clinical investigations that have not already been acquired in compliance with the ordinary procedures for the supply of goods, will also be paid by the manufacturer. The quantities of Medical devices for the Clinical investigation need to be adequate for the number of cases being treated.

4.2 The Medical devices for the Clinical investigation shall be sent by the Sponsor to the Organisational Unit identified by the Entity, which will record them, store them appropriately and deliver them to the Principal Investigator in accordance with the provisions of the Protocol and the current regulations.

4.3 The Medical devices for the Clinical investigation shall be accompanied by an adequate transport note addressed to the Entity’s Organisational unit, describing the type of medical device, the quantity, batch/serial number/other identification details, storage requirements, expiry date and references to the Clinical investigation (Protocol code, Principal Investigator, and Clinical investigation Centre).

4.4 The Entity and the Principal Investigator shall use the Medical devices and Materials supplied by the Sponsor exclusively in the context of, and to conduct the Clinical investigation. The Entity will not transfer or assign to a third party the Medical devices for the Clinical investigation or the Materials supplied by the Sponsor under the terms of this Agreement.

4.5

(a) (*In the event of collection of the Medical devices by the Sponsor*)

All the expired or otherwise unusable Medical devices or those that have not been used on conclusion of the Clinical investigation will be collected by the Sponsor (or its representative) and will subsequently be disposed of at the Sponsor’s expense.

Or (where applicable)

(b) *(In the case of destruction by the Entity*.)

All the expired or otherwise unusable Medical devices or those that have not been used on conclusion of the Clinical investigation will be fully destroyed by the Entity, at the Sponsor’s expense. The Entity shall provide the Sponsor with certification of disposal, in accordance with current

regulations (Italian Legislative Decree No.152 of 3 April 2006). For the disposal of the Medical devices not used for the Clinical investigation and the related operations, the Sponsor shall pay the Entity the amount indicated in Annex A to this Agreement. This sum will if necessary be itemised on the invoice with the application of VAT at the statutory rate as "ancillary payment for the disposal operations of expired or unused Medical devices for the Clinical investigation".

Art. 5 - Loan

5.1 The Sponsor hereby grants on free loan to the Entity, who accepts pursuant to Articles 1803 et seq. of the Italian Civil Code, the Instrument(s) further described below, together with the relevant materials (the "Instrument") _____ (*description of instrument and value in Euro*). By law, the ownership of the Instrument shall not be transferred to the Entity. The effects of this loan will start from the date of delivery of the Instrument(s) and will terminate on completion of the Clinical investigation, when the Instrument(s) will be returned to the Sponsor at no additional cost to the Entity.

The Parties also agree that any other Instruments that may be considered necessary during the course of the Clinical investigation will be granted on free loan, if the terms and conditions are met, in accordance with the provisions of this Agreement. The Entity and the Sponsor shall make a specific agreement with regard to the loan, or an addendum/amendment to this Agreement, if the Instruments are supplied after this Agreement has been made.

5.2 The Instrument(s) will be accompanied by a declaration of conformity with the European regulations and directives. The Instrument(s) in question shall be inspected by the Entity's technicians in the presence of a representative of the Sponsor, by agreement, in order to check their correct installation and functionality, and compliance with the current regulations. Appropriate documents confirming delivery will be prepared at the time of delivery of the material supplied on loan by the Sponsor to the Entity.

5.3 The Sponsor is responsible for transporting and installing the Instrument(s) and will supply, at its own care and expense, the technical assistance necessary for its operation, together with any consumables needed for its use, at no additional cost to the Entity.

5.4 In accordance with the technical manual for the Instrument the Sponsor shall, at its own care and expense and in collaboration with the Investigator, carry out all the technical works necessary for the proper functioning of the Equipment, such as quality checks, calibration and periodic safety inspections. In the case of malfunctioning or faults in the Instrument, which are promptly reported by the Investigator, the Sponsor shall, either directly or using specialised personnel, carry out the corrective maintenance, repairs or substitute the damaged equipment with an identical Instrument.

5.5 The Sponsor also declares that the instruments are covered by third-party liability and fire insurance.

5.6 The Instrument(s) will be used by the personnel of the Entity and/or by the patients solely for the purposes of the Clinical investigation, in accordance with the Protocol. The Entity shall keep and store the Instrument(s) with reasonable diligence and necessary care and will not use it/them for any purpose other than the one indicated above, nor will it transfer the use of the Instrument(s) to a third party, not even temporarily, nor allow it/them to be used for free or for payment, and shall return the Instrument(s) to the Sponsor in the condition in which it/they was/were delivered, except for normal wear and tear from use.

5.7 The Sponsor may demand the immediate return of the Instrument(s) if it/they is/are used improperly or in a way that differs from the provisions of this Agreement, and may demand

compensation for damages. The Sponsor is liable for any loss or damage that may be caused to persons or property in relation to the use of the equipment, if due to flaws in the equipment.

5.8 If the Instrument(s) is lost, stolen or mislaid the Entity shall, as soon as it becomes aware of the incident, make a formal complaint to the relevant public authority and shall inform the Sponsor of the incident at the same time. In all other cases of damage or destruction the Entity will inform the Sponsor as soon as it becomes aware of the incident. Any fraudulent or unauthorised use must be reported immediately by the Principal Investigator to the Sponsor. In the case of irreparable damage or theft of the Instrument(s) the Sponsor will arrange to replace it/them at no additional cost to the Entity unless the incident was caused by fraud or gross negligence by the Entity.

5.9 With regard to Instruments that may be handled or managed directly by the patient/parents/legal guardians (such as electronic diaries) the Sponsor acknowledges that the Entity declines all liability for any tampering, damage or theft of the Instruments caused by the patients/parents/legal guardians. In the event of faults and/or loss of the equipment by the person taking part in the trial, the Sponsor shall replace the equipment at its own expense; the Entity is responsible for delivering the equipment to the recipient, and for registering and delivering the instructions from the Sponsor and for collecting the equipment if the patient exits the trial for any reason; the Entity is also responsible for promptly informing the Sponsor if the equipment is not returned by the patient taking part in the trial.

5.10 Authorisation for the free loan of the Instrument(s) will be/has been granted by the Entity in accordance with its own internal procedures.

Art. 6 – Consideration

6.1 The remuneration agreed for each eligible, assessable patient whose treatment has been completed according to the Protocol and for whom the related CRF/eCRF has been duly compiled, including all the costs incurred by the Entity in execution of this Clinical investigation and the costs to cover all the related activities, is €_____ + VAT (*if applicable*) per patient (a total of € _____ +VAT (*if applicable*) for ____ patients) as specified in more detail in the Budget annexed in Annex A, Part 1.

6.2 The Sponsor will pay the amount due under the terms of this article on the basis of a valid statement of account/supporting document agreed between the Parties. The remuneration of the above amount will be paid with the frequency indicated in the Budget (Annex A) on the basis of the number of patients involved during the period, the treatments carried out according to the Protocol, and in the presence of the duly completed CRF/eCRF approved by the Sponsor/CRO based on the activities carried out.

6.3

(a) (*If the tests are done by a centre external to the Entity)*

All the laboratory/instrument tests indicated in Annex A, required by the Protocol and approved by the Ethics Committee, will not burden the Entity as they will be carried out centrally.

Or

(b) (*If the tests are carried out on the Entity's premises*)

All the laboratory/instrument tests and any other services or additional activities not covered by the price agreed per eligible patient, and requested by the Sponsor as approved by the Ethics Committee and Competent Authority and as detailed in Annex A Part 2, shall be reimbursed and invoiced by the Sponsor/CRO in addition to the price paid for each eligible patient.

6.4 The Entity will not receive any remuneration for patients who cannot be assessed due to failure to observe the Protocol, violation of the rules of Good Clinical Practice or failure to comply with the laws applicable to Clinical investigations on medical devices. The Entity will have no right to receive any remuneration for any patient enrolled after notification of interruption and/or conclusion of the Clinical investigation by the Sponsor/CRO, or any number beyond the maximum number of patients stipulated under the terms of this Agreement, if not agreed with the Sponsor.

6.5 The Sponsor/CRO shall also reimburse the Entity with all the additional costs of medical/diagnostic activities, including hospital admissions, which are not provided for in the Protocol or amendments to the Protocol, and which are not already covered by the above payments, if such activities are essential for the proper clinical treatment of a patient undergoing the Clinical investigation. The reimbursement will only be paid on condition that such activities and costs have been properly communicated, with justification, and have been documented in writing to the Sponsor/CRO and approved in writing by the Sponsor/CRO, and provided that the patient's personal data is communicated in anonymised form.

6.6 If, during the Clinical investigation, it is necessary to increase the financial support to the Entity, the Sponsor may supplement this Agreement by authorising the appropriate increase to the attached Budget.

6.7 In accordance with the 2018 Budget Act (paragraph 909) requiring mandatory e-invoicing for sales of goods and services among private individuals, the Entity shall issue invoices in XML (Extensible Markup Language) format. Invoices are to be sent through the interchange system (SDI).

The Sponsor/CRO shall provide the data necessary for the issue of the e-invoice:

COMPANY NAME _____

RECIPIENT CODE/CERTIFIED EMAIL: _____

TAX CODE _____

VAT no. _____

6.8 The payments made for the Entity's services (i) represent the fair market value for those services, as they reflect the tariff scale applied by the Entity, (ii) were negotiated under normal market conditions, and (iii) were not agreed on the basis of the volume or value of prescriptions or in reference to those prescriptions or other financial activities between the Parties. Neither the Entity nor the Principal Investigator shall request any compensation or reimbursement from any other party in return for the activities performed or costs incurred by including the Patients in the Clinical investigation , which the Sponsor/CRO is obligated to pay for.

6.9 *(If provided for in the Protocol and if the legal conditions are met)*

The Sponsor/CRO will also provide patients taking part in the Clinical investigation with the possibility of reimbursement of out-of-pocket expenses incurred in relation to each visit made to the Entity, according to the procedures, maximum amounts and permitted expenses approved in advance by the Ethics Committee. Costs may only be reimbursed by the administration office of the Entity, which will implement its own procedures. Each patient will submit receipts for the expenses incurred in visiting the Entity; for the purposes of obtaining reimbursement from the Sponsor/CRO, the list will be anonymised by the Entity. Considering the duration of the trial, the Entity will agree the terms for submission to the Sponsor/CRO of the statement of account based on the receipts for patients' expenses presented to the Entity during the treatments carried out in the reference period. The Sponsor may check the sums claimed by comparing them against the visits completed by the

patients and will make the related payments to the Entity. It will then be the responsibility of the Entity to arrange to reimburse the sums to each patient in accordance with the amounts in the table contained in the Budget in Annex A, Part 2".

If provided for in the Protocol, reimbursements may be offered for the carers of patients who are unable to travel alone, for example children, or vulnerable patients.
The costs relating to items not listed in Annex A will not be reimbursed.

Art. 7 - Duration, termination and cancellation

7.1 This Agreement shall take effect from the date of the last signature ("Effective Date") and shall remain in force until conclusion of the Clinical investigation at the Entity, as provided for in the Protocol, subject to any amendments agreed by the Parties. Notwithstanding the above, this Agreement shall be effective following the authorisation, where applicable, by the Competent authority and local authorisations/permits, where applicable.

7.2 The Entity may terminate this Agreement in writing with notice of 30 days, sent to the Sponsor/CRO by registered post or certified email, in the following cases:

- insolvency of the Sponsor/CRO, proposal of composition arrangements, also extrajudicially, with the creditors of the Sponsor or the commencement of enforcement action against the Sponsor/CRO. If the situation indicated above relates to the CRO, the Sponsor is obligated to take over from the CRO and to continue the activities, unless the intervention of another CRO – approved by the Entity – is obtained to replace the insolvent CRO;
- the sale of all or part of the assets of the Sponsor/CRO to the creditors or the agreement of a moratorium with creditors.

The notice will take effect from the time when the Sponsor/CRO receives the above communication.

7.3 The Sponsor/CRO, in accordance with Article 1373(2) of the Italian Civil Code, may terminate this Agreement at any time, for justified reasons, by sending written 30-day notice by registered post or certified email. The notice will take effect from the time when the Entity receives this communication.

The termination by the Sponsor/CRO will not affect the obligations assumed and costs paid by the Entity on the date of notification. In particular, the Sponsor/CRO will pay the Entity all the documented, non-revocable expenses it has incurred in order to ensure the correct, efficient execution of the Clinical investigation, (*where applicable*, including the costs incurred by the Entity towards the patients/participants), and all the payments accruing up until that time.

In the case of early termination, the Sponsor may, as the original owner, receive all the complete and partial data and results obtained by the Entity during the Clinical investigation and also thereafter, if deriving from or related to the Clinical investigation.

7.4 Either Party to this Agreement may interrupt the Clinical investigation at any time with immediate effect, in accordance with the provisions of Article 2 paragraph 5, if it has a valid, documentable reason to consider that the continuation of the Clinical investigation could pose an unacceptable risk to patients' health and safety. If the Clinical investigation is interrupted, the Sponsor/CRO will pay the Entity the expenses and payments accrued and documented up until that time.

7.5 It is also agreed that the early termination of this Agreement shall not give either Party any right to claim from the other Party any compensation or requests for payment other than those already agreed.

7.6 This Agreement shall cease to have effect automatically pursuant to Article 1454 of the Italian Civil Code in the event that either Party has not fulfilled one of its principal obligations as provided for herein, within 30 days from a written notice to perform sent by the other Party.

The provisions of Article 1218 et seq. of the Italian Civil Code shall apply in any event.

7.7 If this Agreement is terminated for reasons not due to breach of contract by the Entity, the Entity shall have the right to reimbursement of the expenses incurred in relation to the Clinical investigation prior to receipt of the notice of termination, and to payment for the services in proportion to the activities completed up until the time of termination. The Entity will repay the Sponsor/CRO any amounts already paid in relation to activities that were not completed.

7.8 In all cases of interruption or termination of this Agreement, full precautions will be taken to protect the patients already involved, in accordance with the protocol approved by the Ethics Committee, and continuity of treatment shall be guaranteed if considered clinically necessary.

Art. 8 - Insurance cover

8.1 The Sponsor/CRO confirms that it has taken out a third party liability insurance policy (no. _____, with the insurer _____) to cover the risk of damage to patients from taking part in the Clinical investigation, in accordance with Article 3 letter n. of M.D. of 2/08/2005. The Ethics Committee considers that the insurance policy complies with the provisions of the law and adequately protects the patients taking part in the Clinical investigation.

8.2 Subject to the provisions of law no. 24 of 8 March 2017, the insurance cover provided by the Sponsor is guaranteed with regard to the civil liability of the Sponsor, the healthcare facility at which the Clinical investigation will take place, the Principal Investigator, and the other investigators involved at the Entity's Centre.

8.3 The Sponsor is liable for any consequences resulting from any present or future deficiencies in the insurance cover mentioned above.

8.4 In particular, in the event that the Sponsor intends to withdraw from the Agreement, the Sponsor warrants that the insurer shall in all cases guarantee the cover of the patients already included in the clinical trial also during the continuation of the Clinical investigation.

8.5 The Entity is required to disclose the existence of MEDMAL policies (to cover the Entity and the medical staff using the device) in accordance with article 1910 of the Italian Civil Code.

Art. 9 - Final report and use of results

9.1 The Sponsor will publish the results of the trial even if the results are negative.

9.2 The sponsor is liable for preparing the final clinical report and for sending a summary of the results of the Clinical investigation to the Principal Investigator and Ethics Committee by the legal deadline.

9.3 All the data deriving from the execution of the Clinical investigation and in pursuit of its objectives, processed in accordance with Article 11, and the results thereof, are the exclusive property of the Sponsor.

If the Sponsor takes action to file an application for a patent relating to inventions obtained during the course of the Clinical investigation, the Entity and the Principal Investigator shall provide all the assistance and documentary support necessary for that purpose.
This does not affect the inventor's legal rights as recognised author.

9.4 The Parties acknowledge that each will remain the owners of the industrial and intellectual property rights to their background knowledge and to the knowledge developed or obtained during the Clinical investigation, regardless and independently of the conduct of the Trial and its objectives (sideground knowledge).

9.5 The provisions of this article will remain valid and binding even after termination or cancellation of this Agreement.

Art. 10 - Secrecy and dissemination of data

10.1 By signing this Agreement, the Entity undertakes to treat as private and confidential all the technical and commercial information contained in the documentation and trial materials provided by the Sponsor/CRO and/or developed during the Clinical investigation and in pursuing the objectives thereof, which may be classified as "Commercial Secrets" within the meaning of articles 98 and 99 of the Industrial Property Code (Italian Legislative Decree 30/2005, as amended by Italian Legislative Decree 63/2018 enacting Directive EU 2016/943), and shall take all the contractual, technological or physical measures necessary to protect such information, also with regard to their own employees, contractors, subcontractors, successors or assigns.

The Sponsor/CRO also represents and warrants as follows:

(i) the Commercial Secrets of the Sponsor/CRO have been acquired, used and disclosed legally and there are not – as far as is known to the Sponsor and/or to the CRO – any legal actions, disputes, claims for compensation or indemnity, whether judicial or extrajudicial, brought by any third party claiming ownership of such secrets.

(ii) Therefore, the Sponsor/CRO shall indemnify the Entity in respect of any legal actions, complaints, claims for compensation or indemnity, whether judicial or extrajudicial, brought by any third party claiming ownership to such secrets.

In turn, by signing this Agreement, the Sponsor/CRO undertakes to treat as private and confidential all the technical and commercial information contained in the documentation and trial materials provided to the Entity, which may be classified as "Commercial Secrets" within the meaning of articles 98 and 99 of the Industrial Property Code, and shall take all the contractual, technological or physical measures necessary to protect such information, also with regard to its own employees, contractors, subcontractors, successors or assigns.

The Entity also represents and warrants as follows:

(iii) the Commercial Secrets of the Entity have been acquired, used and disclosed legally and there are not – as far as is known to the Entity – any legal actions, disputes, claims for compensation or indemnity, whether judicial or extrajudicial, brought by any third party claiming ownership of such secrets.

(iv) Therefore, the Entity shall indemnify the Sponsor in respect of any legal actions, complaints, claims for compensation or indemnity, whether judicial or extrajudicial, brought by any third party claiming ownership to such secrets."

10.2 The Parties are obligated to adequately and accurately disclose and publish the results of the Clinical investigation and to adequately disclose the results of the Clinical investigation to the patients taking part and to the patients' representatives. Under the terms of the applicable regulations, the Sponsor/CRO is required to publish the results of the Clinical investigation even if negative, as soon as they become available from all the participating Centres and in any case no more than 12 months after conclusion of the Clinical investigation.

Pursuant to Article 5(2) (c) of M.D. of 8 February 2013, the Principal Investigator has the right to disseminate and publish, without limitation, the results of the Clinical investigation obtained from the Entity, in accordance with the current laws on the confidentiality of sensitive data, data protection and intellectual property protection, and in accordance with the terms and conditions of this Agreement.

10.3 To ensure that the data processing is correct and accurate, the Principal Investigator will send the Sponsor/CRO a copy of the document to be presented or published, at least 60 days before it is presented or published. The Sponsor shall have 60 days from receipt of the manuscript within which to suggest amendments to the Principal Investigator. If issues arise in relation to the scientific integrity of the document and/or issues regarding regulatory aspects, patents or the protection of intellectual property, the Sponsor/CRO will review the document together with the Principal Investigator. The Principal Investigator agree to make the changes suggested by the Sponsor, or to take into account the Sponsor's suggestions in the publication or presentation, but only if necessary to protect the confidentiality of the personal data and information and to protect intellectual property, provided that the amendments do not conflict with the reliability of the data, or the rights, safety and well-being of the patients.

10.4 The Sponsor/CRO acknowledge that they do not have the right to request the deletion of the information contained in the document and may not modify its contents, except where such requests and amendments are necessary for the purposes of scientific validity, data confidentiality, data protection and the protection of intellectual property.

10.5 The Sponsor/CRO may, for the purposes of presenting a patent application and if necessary, ask the Principal Investigator to delay the publication or presentation of the document by a further 90 days.

(*For multi-centre Clinical investigations*) The Principal Investigator may not publish the data of his or her own Centre until such time as all the results of the Clinical investigation have been published in full or for at least 12 months from conclusion of the Clinical investigation, its interruption or early termination.

If a publication containing the results of a multi-centre Clinical investigation, published by the Sponsor or by the third party designated by the Sponsor is not completed within ____ months (*at least twelve months under the current regulations*) from the end of the multi-centre Clinical investigation, the Investigator may publish the results obtained at the Entity, in accordance with the contents of this Article.

Art. 11 - Data protection

11.1 In executing the contractual activities the Parties shall treat all the personal data they receive for any reason in relation to the Clinical investigation in accordance with the objectives of the foregoing articles and in conformity with the provisions of Regulation (EU) No. 2016/679 of the European Parliament and Council of 27 April 2016, and with the related provisions of law and orders

of national administrations, including any subsequent amendments (collectively the "Data Protection Laws").

11.2 The terms used in this article, in this Agreement, in the informed consent documents and in any other documents used for the purposes of the Clinical investigation shall be construed and utilised in accordance with the meanings given in Annex B.

11.3 The Entity and Sponsor are independent data controllers for the purposes of article 4 (paragraph 17) of the GDPR.

(Omit the following paragraph if the CRO is managing every aspect of the Clinical investigation instead of the Sponsor, assuming the ownership of the related treatments). The CRO ____ is the Data Processor for the purposes of Article 28 GDPR, in reference to the ownership of _____.

11.4 For the purposes of the Clinical investigation, personal data relating to the following categories of data subject will be processed: persons taking part in the Clinical investigation; persons operating on the Parties' behalf. Such data subjects will be appropriately informed of the processing of their data. For the purposes of the Clinical investigation, the following types of personal data will be processed: the data referred to in article 4 paragraph 1 of the GDPR; data classified as "sensitive" – and in particular, data relating to health, sexual preferences and genetic data – referred to in Article 9 GDPR. Such data shall be processed in accordance with the principles of legality, fairness, transparency, adequacy, relevance and necessity as contained in Article 5 paragraph 1 of the GDPR.

11.5 The Sponsor may send the data to other affiliates of the Sponsor's group and to third parties operating on its behalf, including those abroad, in countries outside of the EU that do not offer the same level of data protection as is guaranteed in Europe. In such a case Sponsor is responsible for taking all the measures necessary to guarantee an adequate level of data protection.

11.6 The Parties warrant that the persons authorised by them to process personal data for the purposes of the Clinical investigation will comply with the principles in place to safeguard data protection and the right to confidentiality, and that any persons having access to the personal data will be obligated to process the data in accordance with the instructions given, in accordance with this article, by the data controller.

11.7 The Principal Investigator has been identified by the Entity as a person authorised for the data processing for the purposes of Article 29 GDPR and as a designated party for the purposes of Article 2 *quaterdecies* of the Code.

11.8 The Principal Investigator shall provide clear, complete information to all patients before the Clinical investigation starts (also before the preliminary phases or screening) regarding the nature, purpose, results, consequences, risks and methods of the processing of personal data; in particular all patients must be informed that the national and international authorities and the Ethics Committee may, in connection with the monitoring, checking and control of the Clinical investigation, have access to the related documentation and also to the original healthcare records of the patient, and that the data may also be accessed by the monitors and auditors in connection with their respective duties.

11.9 After the patient has been duly informed, the Principal Investigator shall obtain the consent form for participation in the Clinical investigation and also the consent to the processing of personal data. The Entity is responsible for keeping the consent forms.

11.10 If either Party discovers a data protection breach, the other Party shall be informed within 48 hours from the breach having been verified, without affecting the Party's independent assessment

of the existence of the conditions and fulfilment of the obligations contained in Articles 33 and 34 GDPR.

Art. 12- Amendments

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

12.2 This Agreement may only be amended with the written consent of both Parties. Any amendments will be contained in an addendum to this Agreement and will take effect from the date of signature, unless agreed otherwise by the Parties.

Art. 13 - Anticorruption provisions

13.1 The Entity and the Sponsor/CRO will comply with the anticorruption laws applicable in Italy.

13.2 The Sponsor confirms that it has carried out supervisory and control activities to ensure compliance with, and implementation of, the provisions of Italian Legislative Decree No. 231 of 8 June 2001 and, where applicable and not conflicting with laws in Italy, the principles of the US Foreign Corrupt Practices Act and its subsequent amendments. The Entity and its clinical and administrative facilities undertake to cooperate in good faith, within the limits of the provisions of Italian legislation as above, with the personnel and the management of the Sponsor in order to facilitate the full and correct implementation of the obligations that derive therefrom and the implementation of the operating procedures developed by the Sponsor for that purpose.

13.3 For the purposes of Italian Law 190 of 6 November 2012 ("Anticorruption Act") as amended, the Entity confirms that it has adopted the Three-Year Anti-corruption Plan.

(*If applicable and if not conflicting with current regulations)* The Sponsor declares that it has adopted its own code of ethics which can be viewed at the web page (…) *(insert link to site)*

13.4. The Entity and the Sponsor shall immediately inform each other of any violation of this article by the other Party, of which they become aware, and will provide full information and documents, for all the appropriate investigations.

13.5 The CRO and the Sponsor may disclose the terms of this Agreement or any amendments to this Agreement for any legitimate purpose, within the limits of the data protection laws.

13.6 The violation of any provisions of this article will constitute serious breach of this Agreement pursuant to Article 1456 of the Italian civil code, if the relationship of trust between the Parties is affected.

Art. 14 - Transfer of rights, assignment of contract and subcontracting

14.1 This Agreement is fiduciary in nature and therefore the Parties may not assign or transfer or subcontract this Agreement to any third party without the prior consent of the other Party. Each Party will allow the other Party to assign and/or transfer all or part of the rights and obligations received directly or indirectly from the signing of this Agreement to a successor or to an affiliated company or to a third party, on condition that the transferee accepts all the terms and conditions herein. Any transfer of rights taking place in the absence of such conditions shall be considered null and void and shall be disregarded.

14.2 In the event of a change of name of the Entity, no amendment to this Agreement shall be necessary. However, the Entity is required to duly inform the Sponsor/CRO of its change of name.

Art. 15 - Fiscal obligations

15.1 This Agreement is signed by digital signature in accordance with Article 24 of Italian Legislative Decree 82/2005, as required by Article 15, paragraph 2 *bis* of Italian Law 241/1990, as amended by Article 6, of Italian Decree Law No. 179 of 18/10/2012, converted into Law No. 22 of 17/12/2012. All the taxes and duties relating to or resulting from the stipulation of this Agreement, including the revenue stamp on the digital original as referred to in Article 2 of the table in Annex A – tariff part I of Italian Presidential Decree 642/1972, and the registration tax, must be paid in accordance with the applicable regulations.

15.2 Under Article 7 *ter* of Italian Presidential Decree 633/1972 as amended, the contractual services are subject to VAT, as they are rendered to a taxable person based in Italy. [*Alternatively* Pursuant to Article 7 *ter* of Italian Presidential Decree 633/1972 as amended, the contractual services will be invoiced without VAT, as the local establishment requirement does not apply.]

Art. 16 – Governing law and forum

16.1 This Agreement is governed by the laws of Italy.

16.2 The court in the place of execution of this Agreement shall have sole jurisdiction in respect of any disputes that may arise in relation to the interpretation, application and execution of this Agreement, subject to the Parties' undertaking to attempt an extrajudicial conciliation before referring the matter to the court.

_____, __/__/_____

For the Sponsor/CRO

President / CEO / Legal Representative

Dr. _____

Signature _____

_____, __/__/_____

For the Entity

Director-General/CEO/Legal Representative or deputy

Dr. _____

Signature _____

The Parties confirm that every part of this Agreement has been accepted and therefore the provisions of Article 1341 of the Italian Civil Code will not apply.

_____, __/__/_____

For the Sponsor/CRO
President / CEO / Legal Representative
Dr. _____
Signature _____

For the Entity
Director-General/CEO/Legal Representative or deputy
Dr. _____
Signature _____

ANNEX A - BUDGET ANNEXED TO FINANCIAL AGREEMENT

Details of the information to be included in the budget annexed to the financial agreement are given below.

A1. Reference information for the Clinical investigation

- Title of Protocol,
- Protocol code, version and date,
- Sponsor (*name, address, name of contact, telephone numbers, email address*),
- CRO (if applicable) (*name, address, name of contact, telephone numbers, email address*)
- Principal Investigator (*insert name, centre, address and telephone and email contacts)*
- Number of patients expected at international, national and centre level (*state whether or not the enrolment is competitive*)
- Duration of trial

A2. Costs and payments

Part 1 - Fixed costs and payment per patient enrolled

Include, by way of example, the following items:

- Fixed costs for the Ethics Committee (*attach copy of the bank transfer*) (Coordinating centre for Clinical investigation on Medical devices, Satellite centre for Clinical investigation on Medical devices, Amendments)
- Supply of the Experimental medical device and/or of any other materials required for the Clinical investigation provided that there are no extra costs for the National Health Service (diagnostics kits, medical devices, etc.)
- Gross payment for enrolled patient: € _____+ VAT (*include multiple payments for studies that require different payments for each "arm" of the protocol*)
- Payment per Investigation Centre for each completed patient (Payment for enrolled patient - company overheads - all the costs incurred by the Entity for the Clinical investigation[1]): € _____ + VAT.
- Interim financial phases (if the patients do not complete the trial procedure): Examination: payment per patient (Examination no. ____ € ____ + VAT; Contacts € _____ + VAT; Examination no.__ € ____ + VAT)
- (*only include this paragraph if there are no extra costs referred to in part 2*). All the reimbursable costs of the trial, including those covered by the contribution per patient involved, shall not lead to any extra costs payable by the National Health Service (for example, there are no additional services, the instrumental and laboratory tests are routine for the patients in the trial, or the instrumental tests are routine for the patients in the trial and the lab tests will be carried out with diagnostic kits supplied by ____ or the lab tests will be done at a centralised external laboratory).

Part 2 Additional costs for instrumental tests and/or lab tests to be carried out according to the Tariff

- *Breakdown of additional costs* (the amounts payable for the services may be updated or revised following decisions/measures taken by the region of _____ and will apply from the effective date of those decisions/measures):

[1] • general administrative costs, costs sustained for the management of the MD subject to the Clinical investigation

- TARIFF CODE	- DESCRIPTION OF TEST	- NO. OF TESTS per patient	- AMOUNT € _____+ VAT

Alternatively

- Declaration (with related justification) stating that the trial shall not lead to any extra costs payable by the National Health Service (for example, the instrumental and laboratory tests are routine for the patients in the trial, or the instrumental tests are routine for the patients in the trial and the lab tests will be carried out with diagnostic kits supplied by _____ or the lab tests will be done at a centralised external laboratory _____).

Part 3 Reimbursement of costs for patients/carers included in the Clinical investigation: (*if applicable*)

List the type of reimbursement of travel expenses including taxi/overnight accommodation/meals, upon submission of receipts or other supporting documents.

A3. Insurance cover:

- Specify (policy number, start date, expiry date, cover limits for each protocol and patient, tail coverage, any excess that cannot be claimed against third injured party, exclusions) ……

A4. Liquidation and invoices

- The payment must be made within _____ days (*indicate*) from receipt of the invoice.
- The invoice must be issued at the required intervals _____ (*quarterly/half yearly/annually or according to milestones)* based on the amounts accruing during the reference period, and the request for invoice by the Sponsor/CRO.

ANNEX B - PERSONAL DATA PROTECTION GLOSSARY

- **Personal data** - means any information relating to an identified, or identifiable, natural person (the "Data Subject").An identifiable natural person is a person who can be identified, directly or indirectly by reference of an identifier such as: a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;
- **Processing -** any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;
- **Pseudonymisation** - the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable individual;
- **Data Controller** - the natural or legal person, public authority, agency or any other entity which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law;
- **Data processor** - a natural or legal person, public authority, agency or other body which processes personal data on behalf of the Data Controller;
- **Consent of the Data Subject** - means any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her;
- **Personal Data Breach** - any breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure, or access to, personal data transmitted, stored or otherwise processed;
- **Medical Data** - personal data pertaining to the physical or mental health of an individual including the provision of medical services, which may reveal information about his or her state of health;
- **Genetic data** - personal data relating to the hereditary genetic or acquired characteristics of an individual which provides unequivocal information about the physiology or health of that individual and which results, in particular, from the testing of a biological sample from the individual in question;
- **Biological sample** - any sample of biological material from which the characteristic genetic data of an individual can be extracted;
- **Sponsor** - the person, company, institution or body that is responsible for starting, managing and/or funding a Clinical investigation;
- **CRO** – the contractual research organisation to which the sponsor may entrust all or part of its competencies relating to Clinical investigations;
- **Monitor** – the party responsible for monitoring the Clinical investigation, appointed by the sponsor/CRO;

- **Auditor** – the party responsible for auditing the conduct of the Clinical investigation as an integral part of quality assurance, appointed by the Sponsor/CRO.