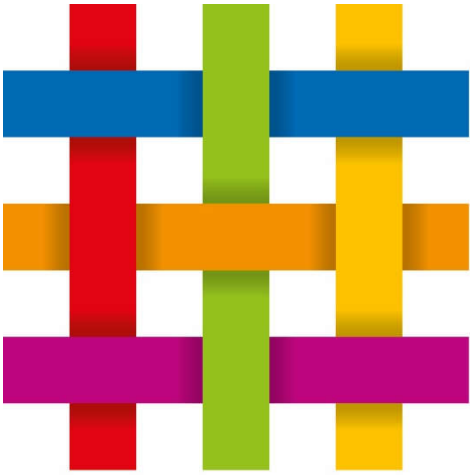


DESCA

Horizon 2020 Model Consortium Agreement

www.DESCA-2020.eu

Table of Content

CONSORTIUM AGREEMENT

THIS consortium agreement (hereinafter the "Consortium Agreement") is based upon REGULATION (EU) No 1290/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2013 laying down the rules for the participation and dissemination in "Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)" (hereinafter referred to as "Rules for Participation"), and the European Commission Multi-beneficiary General Model Grant Agreement and its Annexes, and is made on March 1st, 2021, hereinafter referred to as the "Effective Date".

BETWEEN:

1 - L'UNIVERSITÉ DE BORDEAUX, a Public Establishment for scientific cooperation, located 35, Place Pey Berland, 33000 BORDEAUX, FRANCE, represented by its President, [redacted], **the "Coordinator"**,

2 – RHÖN-KLINIKUM CAMPUS BAD NEUSTADT, (RHÖN-KLINIKUM AG), located in Salzburger Leite 1, 97616 Bad Neustadt a. d. Saale, Germany, VAT number: DE 167834823, represented by [redacted]

3 – CHU HOPITAUX DE BORDEAUX, a Public Health Establishment, which FINESS number is 330781196, which SIRET number is 263 305 823 00019, located at 12 rue Dubernat, 33404 Talence Cedex, represented by [redacted], acting in his capacity of Managing Director, the "Sponsor" or the "CHUB",

4 – INSTITUT KLINICKÉ A EXPERIMENTÁLNÍ MEDICÍNY, established in Videnska 1958/9, PRAGUE 4 14021, Czech Republic, VAT number: CZ00023001, represented by [redacted] acting in his capacity of Director,

5 – MEDIZINISCHE UNIVERSITAT GRAZ, established in AUENBRUGGERPLATZ 2, GRAZ 8036, Austria, VAT number: ATU57511179, represented by [redacted], acting in her capacity of Vice-Rector for Research and International Affairs and [redacted]. [redacted], acting in his capacity of Head of the Department of Internal Medicine,

6 – ALGEMEEN ZIEKENHUIS SINT-JAN BRUGGE-OOSTENDE AUTONOME VERZORGINSINSTELLING, established in RUDDERSHOVE 10, BRUGGE 8000, Belgium, VAT number: BE0266559859, represented by [redacted], acting in his capacity of General Director,

7 – FARAPULSE INC, established in 3715 HAVEN AVENUE SUITE 110, MENLO PARK 94025, United States, represented by [redacted], acting in his capacity of CFO and VP of Commercial Development and Business Operations,

8 – NEMOCNICE NA HOMOLCE, established in Roentgenova 37/2, 150 30 Praha 5, Czech Republic, VAT number: CZ00023884, represented by [redacted], acting in his capacity of Director,

9 – DEUTSCHES HERZZENTRUM MUNCHEN, established in Lazarettstrasse 36, MUNICH 80636, Germany, represented by [redacted], acting in his capacity of Clinical Director,

hereinafter, jointly or individually, referred to as ”Parties” or ”Party”,

relating to the action entitled

Ground-BrEAking Electroporation-based inTervention for Atrial Fibrillation treatment

in short

BEAT-AF

hereinafter referred to as “Project”

WHEREAS:

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Project to the Funding Authority as part of the Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020).

The Parties wish to specify or supplement binding commitments among themselves in addition to the provisions of the specific Grant Agreement to be signed by the Parties and the Funding Authority (hereinafter “Grant Agreement”).

The Parties are aware that this Consortium Agreement is based upon the DESCA model consortium agreement.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1 Section: Definitions

1.1 Definitions

Words beginning with a capital letter shall have the meaning defined either herein or in the Rules for Participation or in the Grant Agreement including its Attachments.

1.2 Additional Definitions

“Access Rights”
means licenses and user rights to Results or Background under the terms and conditions of the Grant Agreement and further specified in this Consortium Agreement.

"Affiliate" or **"Affiliated Entities"**
means an entity controlling, controlled by or under common control with the group of companies controlled by either Party. In this definition "control" means the ability, directly or indirectly, to direct the affairs of another by means of ownership, contract or otherwise.

"Background"
means all information, deliverables, materials, services and other tangible and intangible work product, whether or not they can be protected by intellectual property rights, which are developed or controlled by a Party prior to the Effective Date of this Consortium Agreement or created independently from the Project and this Consortium Agreement without any reference to or use of the other Parties' Confidential Information, intellectual property rights and/or related documentation and which a Party chooses to deliver or make available for use to the other Party for the purposes hereof. A list of Background is described in Attachment 1.

"Coordinator"
means UNIVERSITÉ DE BORDEAUX. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement.

"Clinical Trials"
refers to the trials conducted as part of the Project, i.e. BEAT PAROX-AF and BEAT PERS-AF.

"Confidential Information"
means any technical, commercial and strategic information in whatever form and/or material support exchanged between the Parties under this Consortium Agreement, including but not limited to this Consortium Agreement and its content, the fact that discussions are taking place on any transaction contemplated in this Consortium Agreement, and any analysis, notes or documents drafted or drawn up by a Party on the basis of or relating to the said technical, commercial and strategic information.

"Consortium Body"
means any management body described in the Governance Structure section of this Consortium Agreement.

"Consortium Plan"
means the description of the action and the related agreed budget as first defined in the Grant Agreement and which may be updated by the Steering Committee.

"Data"
means any data, including the Personal Data and / or Clinical Data, that is owned or stored by a Party prior to the commencement of the Project or that is generated under the Project and that is subject to the terms and conditions specified in section 4.7.

- **Clinical Data***:* refers to all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Clinical Data are contained in source documents corresponding to original documents, data, and records (e.g.: hospital records, clinical and office charts, laboratory notes, memoranda, subjects' diaries or evaluation checklits, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, microfiches, photographic negatives, mcrofilm or magnetic media, x-rays, subject files, and records kept at the pharmacy, at the laboratories and at medico-technical departments involved in the clinical trial). Clinical Data shall be made available to another Party in anonymous or pneudonymous

form only. The Clinical Data generated by the Clinical Trials remains under the sole direction, custody and responsibility of the Sponsor.

- **Personal Data***:* means any information relating to an identified or identifiable natural person; an identifiable person being one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

"Funding Authority"
means the body awarding the grant for the Project.

"Defaulting Party"
means a Party which the Steering Committee has identified to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Section 4.2 of this Consortium Agreement.

"Fair and Reasonable conditions"
means appropriate conditions, including financial terms conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the Results or Background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

"GDPR"
means the General Data Protection Regulation 2016/679 adopted by the European Parliament on 27 April 2016 and applicable since 25 May 2018.

"Joint Owners"
means Parties who are co-owners of Results.

"Needed"
means:
For the implementation of the Project:

Access Rights are Needed if, without the grant of such Access Rights, carrying out the tasks assigned to the recipient Party would be technically or legally impossible, significantly delayed, or require significant additional financial or human resources.

For Exploitation of own Results:

Access Rights are Needed if, without the grant of such Access Rights, the Exploitation of own Results would be technically or legally impossible.

"**Results**"
means any tangible or intangible output of the Project, such as data, knowledge or information, that is generated in the Project, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights and excluding Clinical Data.

"Sponsor"
For the purpose of this Project, the Sponsor is CHUB.

2 Section: Purpose

The purpose of this Consortium Agreement is to specify with respect to the Project the relationship among the Parties, in particular concerning the organization of the work between the Parties, the management of the Project and the rights and obligations of the Parties concerning inter alia liability, Access Rights and dispute resolution.

3 Section: Entry into force, duration and termination

3.1 Entry into force

An entity becomes a Party to this Consortium Agreement upon signature of this Consortium Agreement by a duly authorized representative.

This Consortium Agreement shall have effect from the Effective Date identified at the beginning of this Consortium Agreement.

A new entity becomes a Party to the Consortium Agreement upon signature of the accession document (Attachment 2) by the new Party and all the Parties. Such accession shall have effect from the date identified in the accession document.

3.2 Duration and termination

This Consortium Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Parties under the Grant Agreement and under this Consortium Agreement.

However, this Consortium Agreement or the participation of one or more Parties to it may be terminated in accordance with the terms of this Consortium Agreement.
If
- the Grant Agreement is not signed by the Funding Authority or a Party, or
- the Grant Agreement is terminated, or
- a Party's participation in the Grant Agreement is terminated,

this Consortium Agreement shall automatically terminate in respect of the affected Party/ies, subject to the provisions surviving the expiration or termination under Section 3.3 of this Consortium Agreement.

3.3 Survival of rights and obligations

The provisions relating to Access Rights, dissemination and confidentiality, for the time period mentioned therein, as well as for liability, applicable law and settlement of disputes shall survive the expiration or termination of this Consortium Agreement.

Termination shall not affect any rights or obligations of a Party leaving the Consortium incurred prior to the date of termination, unless otherwise agreed between the Steering Committee and the leaving Party. This includes the obligation to provide all input, deliverables and documents for the period of its participation.

4 Section: Responsibilities of Parties

4.1 General principles

Each Party undertakes to take part in the efficient implementation of the Project, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under the Grant Agreement and this Consortium Agreement as may be reasonably required from it and in a manner of good faith as prescribed by Belgian law.

Each Party undertakes to notify promptly, in accordance with the governance structure of the Project, any significant information, fact, problem or delay likely to affect the Project.

Each Party shall promptly provide all information reasonably required by a Consortium Body or by the Coordinator to carry out its tasks.

Each Party shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the other Parties.

Each Party shall comply with all national and local regulatory requirements and laws with regard to clinical study approvals and conduct of the Project.

4.2 Breach

In the event that a responsible Consortium Body identifies a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement (e.g. improper implementation of the Project), the Coordinator or, if the Coordinator is in breach of its obligations, the Party appointed by the Steering Committee, will give formal notice to such Party requiring that such breach will be remedied within 30 (thirty) calendar days from the date of receipt of the written notice by the Party.

If such breach is substantial and is not remedied within that period or is not capable of remedy, the Steering Committee may decide to declare the Party to be a Defaulting Party and to decide on the consequences thereof which may include termination of its participation.

4.3 Involvement of third parties

A Party that enters into a subcontract or otherwise involves third parties (including but not limited to Affiliated Entities) in the Project remains responsible for carrying out its relevant part of the Project and for such third party's compliance with the provisions of this Consortium Agreement and of the Grant Agreement. It has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement and the Grant Agreement.

4.4 Compliance

Each Party shall ensure that its work on the Project complies fully with all applicable local, government and international laws, regulations and guidelines which are effective during the period of the Consortium Agreement, including those governing health and safety, data protection, and where relevant, the use of human subjects and good clinical practice such as those defined by International HSR Standards and those adopted by the Council for International Organizations of Medical Sciences and the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. In this regard, each Party shall maintain the confidentiality, in accordance with section 10 of this Consortium Agreement, of all materials and Data, which are created or used in the course of the Project.

Each Party shall secure and guarantee all necessary Authorizations from the relevant Competent Authority before undertaking any part of the Project requiring such Authorizations and shall, if required, obtain properly signed informed consent and acknowledgement forms from any Patients or their legal guardians who they will involve in the Project. Where any part of the Project takes place in a hospital, the Party involved shall first obtain all necessary approvals and agreements from that hospital.

More specifically, each local principal investigator identified as such in the Consortium Plan and in charge of its trial will implement and monitor the studies according to the protocols which will be established by the clinical trial unit and validated by the trial steering committee and undertaken in this regard to respect the Project plan and its annexes.

The Parties will respect all and any Host Country(ies) and international laws, regulations and technical instructions regarding the use, transfer and storage of Pharmaceutical Products.

The Parties will respect to trial conduct and shall make every reasonable attempt to comply with the study protocol or direction by the Sponsor.

4.5 Supply of FARAPULSE Endocardial Ablation System

4.5.1 FARAPULSE will provide to the Sponsor all the updated and relevant information linked to the Product (as defined below) and additional assistance reasonably required for the submission of Clinical Trials Authorizations at the relevant regulatory authorities. After receipt of the copy of the favorable opinion of the Ethics Committee ("EC"), FARAPULSE agrees to ship directly the agreed-upon number of FARAPULSE Endocardial Ablation Systems (“the Product”) to the relevant Parties (participating sites) on a free of charge basis pursuant to Sponsor’s reasonable instruction reflecting the terms of the Project.

The Sponsor, the participating sites or any relevant Party, shall use these Products supplied by FARAPULSE exclusively for the conduct of the Clinical Trials and will not charge any of the patients participating in the Clinical Trials for the cost of the Products.

In the event that any Clinical Trial is unable to start, is interrupted, or is terminated for any reason, all Products will be returned according to the instructions received from FARAPULSE and at the expense of FARAPULSE. All components of the Products will be returned at the conclusion of the Clinical Trials according to the instructions received from FARAPULSE, at the expense of FARAPULSE.

The Sponsor shall ensure that the participating sites will keep and store the Products supplied by FARAPULSE on conditions in accordance with the Instructions For Use (IFU) of the said Products. The IFU will be included with the Products.

4.5.2 FARAPULSE will manufacture the Products in accordance with requirements under its CE approval.

The Products shall be delivered at the expense of FARAPULSE, which shall retain ownership of them, and shall bear the risks of loss, theft and destruction until receipt by each participating site (“Delivery”). The participating sites shall, promptly upon Delivery, inspect the Products and report any shortage and/or damage to Sponsor and FARAPULSE. As of Delivery, the Sponsor shall bear the risks of loss, theft and destruction for such Products.

The Sponsor or the participating sites shall promptly inform FARAPULSE of the rate of inclusion in the sites, in order for FARAPULSE to provide the Products within the desired deadlines.

4.5.3 With each of the shipment, the packing slip corresponding to the Products must be included and must clearly show the expiration date and the lot number.

4.5.4 Without prejudice to the provisions of section 5 below, FARAPULSE warrants to the Sponsor and the participating sites that the Products as the date of Delivery, substantially conform to FARAPULSE's material published specifications and are free from any defects in material or workmanship through the sterility expiration date stated on the package. This warranty shall not apply to liabilities to the extent resulting from a principal investigator not using Products in accordance with the Protocol or other written instructions of FARAPULSE, or the gross negligence, willful misconduct of a principal investigator.

FARAPULSE will inform the Sponsor of any modification of the manufacturing process or of the specifications that may affect clinical safety or efficacy or require a change in the Instructions for Use arising in the course of Clinical Trials for the lot(s) of Products delivered for the Clinical Trials.

4.5.5 In accordance with European Good Manufacturing Practices in force, FARAPULSE shall be responsible for any recalls or Field Safety Corrective Actions (FSCA) of impacted lots of the Products which did not meet the necessary requirements on the date of Delivery and for informing Sponsor thereof immediately. The operational liabilities in respect of lot recall or FSCA may, however, be delegated to a service-provider under a contract.

To accomplish this, in the event that a lot recall must be undertaken, the Sponsor and each local principal investigator shall cooperate fully with FARAPULSE or the designated service-provider to return the affected Products.

4.6 Device vigilance

The Sponsor shall report any adverse events (each as defined in the Protocol) that arise in relation to the Clinical Trials to (i) the relevant Regulatory Authorities in accordance with the Applicable Laws; and (ii) any overseeing Ethics Committee in accordance with its policies. The other Parties will be promptly informed in writing via the competent Consortium Body.

4.7 Data exchange

The Data recorded during this research will be collected, stored and analyzed in accordance with GDPR.

If a national legislation at one of the Parties requires prior authorization/approval by the national Data protection authority for the intended data collection, data processing and/or data transfer, BEAT-AF Consortium will provide a copy of the authorization to the European Commission. If a declaration of compliance is applicable in Party' country, BEAT-AF Consortium will provide a copy of each compliance of "reference methodology".

The performance of the agreement may give a transfer of personal data as outside the European Union. In agreement of article 46 (2) of the GDPR, the Parties are agreed to concluded standard clauses in attachment.

Each Party will provide adequate measures to ensure Data protection and confidentiality regarding local, national, and international rules on data protection. No information on personal details of patients will be transferred unless such transfer is required by legal authorities. All Data generated will be stored in encrypted and password-locked files behind a secured firewall operating within a clinical hospital or university environment. Physical Data must also be protected by adequate measures.

It is the responsibility of each Party to effect and maintain all inventories and registrations for the Processing of Personal Data as required under Applicable Law. The Parties shall cooperate and assist each other with respect to any data protection impact assessments and/or prior consultations with government authorities that may be required in respect to Processing that is carried out under the Consortium.

Each Party shall notify at the other Parties, in the manner specified in the Consortium Agreement, within thirty-six (36) hours of discovery of a Security Incident related to the Processing of Personal Data under the Agreement. In the course of notification, the concerning Party will provide, as feasible, sufficient information for the other Parties to jointly assess the Security Incident and make any required notification to any government authority within the timeline required by Applicable Law. The Parties will jointly decide on the basis of all available information and Applicable Law if the Security Incident will be considered a Data Security Breach and arrange for notification to data subjects and/or government authorities if required by law. Where the Parties decide that notification is required by law, the Party having suffered the security incident shall be responsible for providing such notification.

The Parties agree that, as between them, the participating sites are best able to manage requests from Study subjects for access, amendment, Transfer, restriction, or deletion of Personal Data. Sponsor shall respond to Clinical Trials subjects' requests for access, amendment, transfer, restriction, or deletion of Personal Data in accordance with Applicable Law. Sponsor acknowledges that in order to maintain the integrity of Clinical Trials results, the ability to amend, restrict, or delete Personal Data may be limited, in accordance with Applicable Law. The Party acknowledges that Clinical Trials subjects may withdraw their informed consent to Clinical Trials participation and their consent to Processing of Personal Data at any time.

All collected Data will be pseudonymized so that Data will never indirectly mention the names of the persons concerned or their addresses. Only the information strictly necessary for the processing and the purpose of the research will be collected and this Data will be kept for the duration of the study until the final report or until the last publication and then archived for the duration in conformity with the regulation in force. The Sponsor may disclose collected Data to regulatory agencies in case of audit. There is no public value in the Data and hence no foreseen need for public access beyond that of the therapist. Nonetheless, it can be considered upon request, according to GDPR or regulatory agencies.

All Clinical Data collected during the trials will be pseudonymized and recorded using specific electronic Case Report Form (eCRF) and complex data associated to the study (data too large and complex to be included in eCRF) to assume patient confidentiality in both numerical databases as required by the personal data protection laws in the various EU countries. Quality assurance will be assured by the organisation of monitoring visits and control of eCRF to evaluate the progress of the study, verify the accuracy and completeness of data and assure that all protocol requirements, applicable local laws and GCP/ICH guidelines are respected. At the end of the study, according to GCP/ICH guidelines, the study closing will be conducted.

5 Section: Liability towards each other

5.1 No warranties

In respect of any information or materials (incl. Results and Background) supplied by one Party to another under the Project, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties.

Therefore,

- the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and
- no Party granting Access Rights shall be liable in case of infringement of proprietary rights of a third party resulting from any other Party (or its Affiliated Entities) exercising its Access Rights.

5.2 Limitations of contractual liability

No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, provided such damage was not caused by a willful act.
Notwithstanding anything to the contrary herein or where such limitation would be prohibited by mandatory provisions of law, in no event shall either Party be liable as between the Parties to the other for any indirect or consequential damages (including any loss of profits, loss of revenue, loss of data, loss of contracts or opportunity) not covered under the civil liability insurance policy arising out of the subject matter or performance of this Agreement.

The terms of this Consortium Agreement shall not be construed to amend or limit any Party's statutory liability.

5.3 Damage caused to third parties

Each Party shall be solely liable for any loss, damage or injury to third parties resulting from the performance of the said Party's obligations by it or on its behalf under this Consortium Agreement or from its use of Results or Background.

In no event shall FARAPULSE be liable to any other Party (the "Other Party"), any principal investigator or any third party for any use, handling or storage by or on behalf of the Other Party of the Product or any loss, claim, damage or liability, of whatsoever kind or nature, which may arise from the Other Party's negligent or wrongful actions, or breach of this Agreement, and each Other Party shall hold FARAPULSE and its officers, employees and agents harmless from any third party claims or any third party liabilities which arise as a result of: (i) the Other Party's use of the Product (including the design and conduct of any of the Clinical Trials), (ii) the Other Party's or any principal investigator's breach of this Agreement or (iii) the Other Party's or any principal investigator's negligence or willful misconduct. The foregoing limitation of liability and agreement to hold harmless shall not apply to any loss, claim, damage or liability resulting from the failure of the Product as delivered to the Other Party to comply with the applicable Good Manufacturing Practices, or from any defect in the Product existing at the time of delivery to the Other Party, or from wrong instructions given in writing by FARAPULSE.

5.4 Force majeure

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement by force majeure.

Each Party will notify the Steering Committee of any force majeure without undue delay. If the consequences of force majeure for the Project are not overcome within 3 (three) months after such notification, the transfer of tasks - if any - shall be decided by the Steering Committee.

6 Section Governance structure

6.1 General structure

The BEAT-AF management structure of the Consortium shall comprise the following Consortium Bodies:

- Steering Committee as the ultimate decision-making body of the consortium;
- Ethics Advisory Board as the advisor body for the execution of the Project which shall report to and be accountable to the Steering Committee;
- The Coordinator as the legal entity acting as the intermediary between the Parties and the Funding Authority. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and this Consortium Agreement;
- The Work Package Leader (WP Leader), whose missions are defined below;
- The Management Support Team.

In addition to the overall governance of the project, BEAT AF will implement a dedicated trials management structure to conduct the two studies:

- Data Safety Monitoring Board;
- Trial Steering Committee;
- Trial Management Team.

6.2 Members

The Steering Committee shall consist of one representative of each Party (hereinafter referred to as “Member”).

Each Member shall be deemed to be duly authorized to deliberate, negotiate and decide on all matters listed in Section 6.3.5 of this Consortium Agreement.

The Coordinator shall chair all meetings of the Steering Committee, unless decided otherwise by the Steering Committee.

The Parties agree to abide by all decisions of the Steering Committee.
This does not prevent the Parties from submitting a dispute for resolution in accordance with the provisions of settlement of disputes in Section 11.8 of this Consortium Agreement.

6.3 Operational procedures for the Steering Committee:

6.3.1 Representation in meetings

Any Member:

- should be present or represented at any meeting;
- may appoint a substitute or a proxy to attend and vote at any meeting;
- and shall participate in a cooperative manner in the meetings.

6.3.2 Preparation and organization of meetings

6.3.2.1 Convening meetings:

The chairperson shall convene ordinary meetings of the Steering Committee at least once (1) a year and conference calls every two (2) or three (3) months. The Chairperson shall also convene extraordinary meetings at any time upon written request of any Member.

6.3.2.2 Notice of a meeting

The chairperson shall give notice in writing of a meeting to each Member as soon as possible and no later than fourteen (14) calendar days preceding an ordinary meeting and seven (7) calendar days preceding an extraordinary meeting.

6.3.2.3 Sending the agenda:

The chairperson shall prepare and send each Member a written original agenda no later than fourteen (14) calendar days preceding the meeting, or seven (7) calendar days before an extraordinary meeting.

6.3.2.4 Adding agenda items:

Any agenda item requiring a decision by the Members must be identified as such on the agenda.

Any Member may add an item to the original agenda by written notification to all of the other Members no later than seven (7) calendar days preceding the meeting.

6.3.2.5

During a meeting of the Steering Committee the Members present or represented can unanimously agree to add a new item to the original agenda.

6.3.2.6

Meetings of the Steering Committee may also be held by teleconference or other telecommunication means.

6.3.2.7

Decisions will only be binding once the relevant part of the minutes has been accepted according to Section 6.3.4.

6.3.2.8

Any decision may also be taken without a meeting if the Coordinator circulates to all Members of the Steering Committee a written document, which is then agreed by the defined majority (see Section 6.3.3) of all Members of the Steering Committee. Such document shall include the deadline for responses.

Decisions taken without a meeting shall be considered as accepted if, within the period set out in article 6.3.4.2, no Member has sent an objection in writing to the chairperson. The decisions will be binding after the chairperson sends to all Members of the Steering Committee and to the Coordinator a written notification of this acceptance.

6.3.3 Voting rules and quorum

6.3.3.1

The Steering Committee shall not deliberate and decide validly unless four/fifths (4/5) of its Members are present or represented (quorum).

If the quorum is not reached, the chairperson of the Steering Committee shall convene another ordinary meeting within fifteen (15) calendar days. If in this meeting the quorum is not reached once more, the chairperson shall convene an extraordinary meeting which shall be entitled to decide even if less than the quorum of Members are present or represented.

6.3.3.2

Each Member of the Steering Committee present or represented in the meeting shall have one (1) vote.

6.3.3.3

A Party which the Steering Committee has declared according to Section 4.2 to be a Defaulting Party may not vote.

6.3.3.4

Decisions shall be taken by a simple majority, except for the following decisions that are taken at the majority of 2/3 of the voters: a change in the Project objectives, partnership composition or allocation of funding between Work Packages. In the event of a tied vote, the Coordinator (as chair) will have an additional vote.

6.3.4 Minutes of meetings

6.3.4.1

The chairperson of the Steering Committee shall produce written minutes of each meeting which shall be the formal record of all decisions taken. He/she shall send draft minutes to all Members within 10 calendar days of the meeting.

6.3.4.2

The minutes shall be considered as accepted if, within fifteen (15) calendar days from sending, no Member has sent an objection in writing to the chairperson with respect to the accuracy of the draft of the minutes.

6.3.4.3

The chairperson shall send the accepted minutes to all the Members of the Steering Committee, and to the Coordinator, who shall safeguard them. If requested the Coordinator shall provide authenticated duplicates to Parties.

6.3.5 Decisions of the Steering Committee

The Steering Committee shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out herein.

The following decisions shall be taken by the Steering Committee:

Content, finances and intellectual property rights

- Proposals for changes to Annexes 1 and 2 of the Grant Agreement to be agreed by the Funding Authority;

- Changes to the Consortium Plan;
- Modifications to Attachment 1 (Background Included);
- Additions to Attachment 3 (List of Third Parties for simplified transfer according to Section 8.5.2);
- Additions to Attachment 4 (Identified Affiliated Entities);
- Strategy for adequate dissemination and exploitation of the Results.

Evolution of the Consortium

- Entry of a new Party to the Consortium and approval of the settlement on the conditions of the accession of such a new Party;
- Withdrawal of a Party from the Consortium and the approval of the settlement on the conditions of the withdrawal;
- Identification of a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement;
- Declaration of a Party to be a Defaulting Party;
- Remedies to be performed by a Defaulting Party;
- Termination of a Defaulting Party's participation in the Consortium and measures relating thereto;
- Proposal to the Funding Authority for a change of the Coordinator;
- Proposal to the Funding Authority for suspension of all or part of the Project;
- Proposal to the Funding Authority for termination of the Project and the Consortium Agreement.

In the case of abolished tasks as a result of a decision of the Steering Committee, Members shall rearrange the tasks of the Parties concerned. Such rearrangement shall take into consideration the legitimate commitments taken prior to the decisions, which cannot be cancelled.

6.4 Coordinator

6.4.1

The Coordinator shall be the intermediary between the Parties and the Funding Authority and shall perform all tasks assigned to it as described in the Grant Agreement and in this Consortium Agreement.

6.4.2

In particular, the Coordinator shall be responsible for:

- Monitoring compliance by the Parties with their obligations;
- Keeping the address list of Members and other contact persons updated and available;
- Collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certification) and specific requested documents to the Funding Authority;
- Preparing the meetings, proposing decisions and preparing the agenda of Steering Committee meetings, chairing the meetings, preparing the minutes of the meetings and monitoring the implementation of decisions taken at meetings;
- Transmitting promptly documents and information connected with the Project to any other Party concerned;
- Administering the financial contribution of the Funding Authority and fulfilling the financial tasks described in Section 7.3;

– Providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.

If one or more of the Parties is late in submission of any project deliverable, the Coordinator may nevertheless submit the other Parties' project deliverables and all other documents required by the Grant Agreement to the Funding Authority in time.

6.4.3

If the Coordinator fails in its coordination tasks, the Steering Committee may propose to the Funding Authority to change the Coordinator.

6.4.4

The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party or of the Consortium, unless explicitly stated otherwise in the Grant Agreement or this Consortium Agreement.

6.4.5

The Coordinator shall not enlarge its role beyond the tasks specified in this Consortium Agreement and in the Grant Agreement.

6.5 Management Support Team

The Management Support Team shall be proposed by the Coordinator. It shall assist the Coordinator for executing the decisions of the Steering Committee as well as the day-to-day management of the Project.

The Management Support Team is composed of:

- **The Project Coordinator** – [redacted] he will be in charge of the overall monitoring of the Project, the relations with the Funding Authority, the Project administration, the due reporting and the financial responsibility. Together with the Project Manager, the Project Coordinator is responsible for day-to-day project management of BEAT AF.

- **The Project Manager** (Université de Bordeaux) - the grant office of IHU Liryc: The Project Manager provides the Parties with professional managerial capacity to lead the actual implementation of the high-level strategic decisions of the Steering Committee on a day-to-day basis. He will be in close contact with all WP Leaders in order to foster interactions between them. The Project Manager will ensure availability of all the information needed for decisions making project's implementation. The Project Manager is in charge of consistently encouraging professional management up to the project success and must keep archives for as long as stipulated in the Grant Agreement.

6.6 Work Package Leader (WP Leader)

A WP Leader of each WP is specified in the Project. The WP Leader shall have the following functions:

- Propagation of WP Results;
- Ensuring the scientific quality of the work within their WP;

- Time schedule management;
- Deliverables and milestones timely achievement;
- Discussion, solving problems with the scientist and participants of the WP;
- Communication with the Project Coordinator and Project Manager about the budget allocated to the Parties involved in the WP;
- Ensuring the flow of communication inside and outside their WP;
- On time delivery of the progress and budget reports to the Coordinator.

6.7 Trials Management Structure

6.7.1 Data Safety Monitoring Board (DSMB)

The DSMB consists of an independent group of experts who monitor patient safety and treatment efficacy data while a Clinical Trial is ongoing. The Board should comprise electrophysiologists experts in atrial fibrillation, and at least one methodologist (trial expert) and one biostatistician with particular expertise in interim analyses and sequential designs. The DSMB composition will be defined at the Project start. It will be responsible for the development of strict procedures for the monitoring of study findings and the detection of adverse events.
The DSMB physically convenes prior to initiation of the study. Thereafter, the frequency of scheduled meetings depends on patient enrolment and safety event rates. However, a yearly scheduled meeting, face to face or through vision conference will be organised. If necessary, additional meetings may be held by conference calls if the DSMB so decides.

6.7.2 A Trial Steering Committees (TSC)

The TSC will be established to act as the oversight body for the Clinical Trial on behalf of the Sponsor. It will be chaired by the Project Coordinator. The TSC consists of a clinical site principal investigator per country, the head of clinical trial unit, a senior Sponsor representative, and CHUB-Euclid key staff (trial project manager, safety officer, methodologist and statistician). The TSC, advised by the Ethics Advisory Board, will elaborate the informed consent and other trial documents for patients. The TSC will meet every six (6) months (possibly with vision conferences) and will report to the Steering Committee.

6.7.3 A Trial Management Team (TMT)

The TMT chaired by the trial coordinating investigator, will be established for the day-to-day management of the Clinical Trial, i.e., operational committee to include trial principal investigators, CHUB-Euclid (trial Project manager, safety officer, data manager, methodologist and statistician), national key staff (trial Project managers and/or clinical research associates). The TMT will monitor the Clinical Trial progress according to qualitative and quantitative performance indictors to be developed by CHUB-Euclid in the TMT charter (e.g. regulatory submission, participant inclusion, on-site monitoring visits, key data entry, lost-to-follow-up participants, logistic circuits, on-site safety reporting). The TMT will conduct monthly teleconferences to discuss Clinical Trial progress, which will be presented afterwards in a TMT report.

6.8 Ethics Advisory Board (EAB)

An Ethics Advisory Board (EAB) will be appointed by the Steering Committee.

The EAB will observe and deal with issues relevant to ethics. Functioning as an academic and patient-driven advisory group, it will evaluate and guide BEAT AF Consortium on all ethics, patient safety and scientific conduct issues. The EAB will safeguard the Project's compliance with all necessary ethical regulations by checking the ethical aspects of the study protocols and standards implemented for patient recruitment and prospective examinations.

All Parties agree to give a proxy to the Coordinator to ensure that the non-disclosure agreement in Attachment 5 shall be executed between the Coordinator and each EAB member. Its terms shall be not less stringent than those stipulated in this Consortium Agreement, and it shall be concluded no later than 30 (thirty) calendar days after their nomination or before any Confidential Information will be exchanged, whichever date is earlier. The Coordinator shall write the minutes of the EAB meetings and prepare the implementation of the EAB's suggestions. The EAB members shall be allowed to participate in Steering Committee meetings upon invitation but have not any voting rights.

7 Section: Financial provisions

7.1 General Principles

7.1.1 Distribution of Financial Contribution

The financial contribution of the Funding Authority to the Project shall be distributed by the Coordinator according to:

- The Consortium Plan;
- The approval of reports by the Funding Authority; and
- The provisions of payment in Section 7.3.

A Party shall be funded only for its tasks carried out in accordance with the Consortium Plan.

7.1.2 Justifying Costs

In accordance with its own usual accounting and management principles and practices, each Party shall be solely responsible for justifying its costs with respect to the Project towards the Funding Authority. Neither the Coordinator nor any of the other Parties shall be in any way liable or responsible for such justification of costs towards the Funding Authority.

7.1.3 Funding Principles

A Party that spends less than its allocated share of the budget as set out in the Consortium Plan or – in case of reimbursement via unit costs - implements fewer units than foreseen in the Consortium Plan will be funded in accordance with its actual duly justified eligible costs only.

A Party that spends more than its allocated share of the budget as set out in the Consortium Plan will be funded only in respect of duly justified eligible costs up to an amount not exceeding that share.

7.1.4 Return of excess payments; receipts

7.1.4.1

In any case of a Party having received excess payments, the Party has to return the relevant amount to the Coordinator without undue delay.

7.1.4.2

In case a Party earns any receipt that is deductible from the total funding as set out in the Consortium Plan, the deduction is only directed toward the Party earning such income. The other Parties' financial share of the budget shall not be affected by one Party's receipt. In case the relevant receipt is more than the allocated share of the Party as set out in the Consortium Plan, the Party shall reimburse the funding reduction suffered by other Parties.

7.1.5 Financial Consequences of the termination of the participation of a Party

A Party leaving the Consortium shall refund all payments it has received except the amount of contribution accepted by the Funding Authority or another contributor. Furthermore a Defaulting Party shall, within the limits specified in Section 5.2 of this Consortium Agreement, bear any reasonable and justifiable additional costs occurring to the other Parties in order to perform its and their tasks.

7.2 Budgeting

The budget set out in the Consortium Plan shall be valued in accordance with the usual accounting and management principles and practices of the respective Parties.

7.3 Payments

7.3.1 Payments to Parties are the exclusive tasks of the Coordinator.

In particular, the Coordinator shall:

- notify the Party concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references
- perform diligently its tasks in the proper administration of any funds and in maintaining financial accounts
- undertake to keep the Funding Authority's financial contribution to the Project separated from its normal business accounts, its own assets and property, except if the Coordinator is a Public Body or is not entitled to do so due to statutory legislation.

With reference to Articles 21.2 and 21.3.2 of the Grant Agreement, no Party shall before the end of the Project receive more than its allocated share of the maximum grant amount from which the amounts retained by the Funding Authority for the Guarantee Fund and for the final payment have been deducted.

Requests by the Parties to the Coordinator for their portion of payments shall be made within thirty (30) days of such request, after EU funds were received by the coordinator.

7.3.2

Funding of costs included in the Consortium Plan will be paid to Parties after receipt by the Coordinator from the Funding Authority in separate instalments as agreed in the Grant Agreement.

- One pre-financing payment. The Commission will make the pre-financing payment to the Coordinator within thirty (30) days, either from the entry into force of the Agreement or from ten (10) days before the starting date of the action, whichever is the latest.
- Interim payments at each reporting period (every eigteen (18) months). The Commission will pay to the Coordinator the amount due as interim payment within ninety (90) days from receiving the periodic report.
- One payment of the balance. The payment of the balance reimburses the remaining part of the eligible costs incurred by the Parties for the implementation of the action.

8 Section: Results

8.1 Ownership of Background

Each Party shall retain all right, title and interest in and to all of its Background.

8.2 Ownership of Results

Results are owned by the Party that generates them.

8.3 Joint ownership

Joint ownership is governed by Grant Agreement Article 26.2 with the following additions:

Unless otherwise agreed:

- each of the joint owners shall be entitled to use their jointly owned Results for non-commercial research activities on a royalty-free basis, and without requiring the prior consent of the other joint owner(s); and
- each of the joint owners shall be entitled to otherwise exploit the jointly owned Results and to grant non-exclusive licenses to third parties (without any right to sub-license), if the other joint owners are given:
  (a) at least 45 calendar days advance notice; and
  (b) Fair and Reasonable compensation to be agreed in writing between the Parties.

8.4 Clinical Data

The Parties acknowledge that the Clinical Data as described in the protocol that will be implemented under the Project will be under the sole direction, custody and responsibility of the CHUB, in its capacity as Sponsor, which will be free to exploit them in the frame of patient consent and in accordance with all applicable laws, provided that the Party that generated each such Clinical Data at its site may continue to use it for purposes of non-commercial research, education and patient care, being specified that concerning non-commercial research, the said Party cannot take the unilateral decision to divulge these Clinical Data.

The Sponsor grants to the other Parties a right of use of the previously pseudonymized Clinical Data, insofar as this is necessary for the realization of the Project and declares as such having obtained the authorizations or consents and proceeded to the necessary formalities. For FARAPULSE, this right of use must be in accordance with Attachment 6 of the Consortium Agreement.

8.5 Transfer of Results

8.5.1

Each Party may transfer ownership of its own Results following the procedures of the Grant Agreement Article 30.

8.5.2

It may identify specific third parties it intends to transfer the ownership of its Results to in Attachment 3 to this Consortium Agreement. The other Parties hereby waive their right to prior notice and their right to object to a transfer to listed third parties according to the Grant Agreement Article 30.1.

8.5.3

The transferring Party shall, however, at the time of the transfer, inform the other Parties of such transfer and shall ensure that the rights of the other Parties will not be affected by such transfer. Any addition to Attachment 3 after signature of this Agreement requires a decision of the Steering Committee.

8.5.4

The Parties recognize that in the framework of a merger or an acquisition of an important part of its assets, it may be impossible under applicable EU and national laws on mergers and acquisitions for a Party to give the full forty-five (45) calendar days prior notice for the transfer as foreseen in the Grant Agreement.

8.5.5

The obligations above apply only for as long as other Parties still have - or still may request - Access Rights to the Results.

8.5.6 Option Right

The Parties agree that FARAPULSE, only in the field of the treatment of atrial fibrillation and other cardiac arrhythmias, shall have an exclusive option right to obtain an exclusive license with respect to the commercial exploitation all Results or an assignment of such Results, as follows:

a. As soon as reasonably possible after their creation, FARAPULSE shall be notified in writing of all Results arising the Project.

b. At any time during the term of the Consortium Agreement or for thirty (30) days thereafter (the "Option Term"), FARAPULSE may notify the owner of any Results that it wishes to exercise its option right with respect to such Results. Upon receipt of such notice by the owner of such Results, FARAPULSE and the owner of such Results shall enter into good faith negotiations for the terms of an exclusive license agreement on market terms or assignment to FARAPULSE of such Results for one hundred and twenty (120) days. Any such agreement shall reflect Fair and Reasonable conditions.

c. If no agreement is reached during the one hundred and twenty (120) day negotiation period, despite both parties negotiating in good faith, then the Results owner will be free to license such Results to a third party provided that they do not do so on more favourable terms than those last offered to FARAPULSE.

d. If, during the Option Term, a Party wishes to license or assign any Results to a third party and FARAPULSE has not exercised its Option Right in respect of those Results, then the owner of the Results will notify FARAPULSE at least thirty (30) days before entering into any such agreement, so that FARAPULSE can consider whether it wishes to exercise its Option Right or not as soon as reasonably possible.

8.6 Dissemination

8.6.1

For the avoidance of doubt, nothing in this Section 8.4 has impact on the confidentiality obligations set out in Section 10.

8.6.2 Dissemination of own and jointly owned Results

8.6.2.1

Each Party will not make any publication or communication relating to the Clinical Trials without the prior written consent of the Sponsor, and in no case before the first publication of the Sponsor. The Results not related to the Clinical Trials carried out will be subject to the procedure laid down in Article 8.6.2.2.

8.6.2.2

During the Project and for a period of one (1) year after the end of the Project, the dissemination of own and jointly owned Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the procedure of Article 29.1 of the Grant Agreement subject to the following provisions.

Prior notice of any planned publication shall be given by written to the other Parties at least forty-five (45) calendar days before the publication. Any objection to the planned publication shall be made in accordance with the Grant Agreement in writing to the Coordinator and to the Party or Parties proposing the dissemination within thirty (30) calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

8.6.2.3

An objection is justified if

(a) the protection of the objecting Party's Results or Background would be adversely affected

(b) the objecting Party's legitimate interests in relation to the Results or Background would be significantly harmed.

The objection has to include a precise request for necessary modifications.

8.6.2.4

If an objection has been raised the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate measures are taken following the discussion.

8.7

The objecting Party can request a publication delay of not more than 90 (ninety) calendar days from the time it raises such an objection. After 90 (ninety) calendar days the publication is permitted.

8.7.1 Dissemination of another Party’s unpublished Results or Background

A Party shall not include in any dissemination activity another Party's Results or Background without obtaining the owning Party's prior written approval unless they are already published.

8.7.2 Cooperation obligations

The Parties undertake to cooperate to allow the timely submission, examination, publication and defense of any dissertation or thesis for a degree that includes their Results or Background subject to the confidentiality and publication provisions agreed in this Consortium Agreement.

8.7.3 Use of names, logos or trademarks

Nothing in this Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

9 Section: Access Rights

9.1 Background included

9.1.1
In Attachment 1, the Parties have identified and agreed on the Background for the Project and have also, where relevant, informed each other that access to specific Background is subject to legal restrictions or limits.

Anything not identified in Attachment 1 shall not be the object of Access Right obligations regarding Background.

9.1.2
Any Party may add further own Background to Attachment 1 during the Project by written notice to the other Parties. However, approval of the Steering Committee is needed should a Party wish to modify or withdraw its Background in Attachment 1.

9.2 General Principles

9.2.1

Each Party shall implement its tasks in accordance with the Consortium Plan and shall bear sole responsibility for ensuring that its acts within the Project do not knowingly infringe third party property rights.

9.2.2

Any Access Rights granted expressly exclude any rights to sublicense unless expressly stated otherwise.

9.2.3

Access Rights shall be free of any administrative transfer costs.

9.2.4

Access Rights are granted on a non-exclusive basis.

9.2.5

Results and Background shall be used only for the purposes for which Access Rights to it have been granted.

9.2.6

All requests for Access Rights shall be made in writing. The granting of Access Rights may be made conditional on the acceptance of specific conditions aimed at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place.

9.2.7

The requesting Party must show that the Access Rights are Needed.

9.3 Access Rights for implementation

Access Rights to Results and Background Needed for the performance of the own work of a Party under the Project shall be granted on a royalty-free basis, unless otherwise agreed for Background in Attachment 1.

9.4 Access Rights for Exploitation

9.4.1 Access Rights to Results

Access Rights to Results if Needed for Exploitation of a Party's own Results shall be granted on Fair and Reasonable conditions.

Access Rights to Results for internal research activities shall be granted on a royalty-free basis.

9.4.2

Access Rights to Background if Needed for Exploitation of a Party's own Results, including for research on behalf of a third party, shall be granted on Fair and Reasonable conditions.

9.4.3

A request for Access Rights may be made up to 18 (eighteen) months after the end of the Project or, in the case of Section 9.7.2.1.2, after the termination of the requesting Party's participation in the Project.

9.5 Access Rights for Affiliated Entities

Affiliated Entities have Access Rights under the conditions of the Grant Agreement Articles 25.4 and 31.4. if they are identified in Attachment 4 (Identified Affiliated Entities) to this Consortium Agreement.

Such Access Rights must be requested by the Affiliated Entity from the Party that holds the Background or Results. Alternatively, the Party granting the Access Rights may individually agree with the Party requesting the Access Rights to have the Access Rights include the right to sublicense to the latter's Affiliated Entities listed in Attachment 4. Access Rights to Affiliated Entities shall be granted on Fair and Reasonable conditions and upon written bilateral agreement.

Affiliated Entities which obtain Access Rights in return fulfil all confidentiality and other obligations accepted by the Parties under the Grant Agreement or this Consortium Agreement as if such Affiliated Entities were Parties.

Access Rights may be refused to Affiliated Entities if such granting is contrary to the legitimate interests of the Party which owns the Background or the Results.

Access Rights granted to any Affiliated Entity are subject to the continuation of the Access Rights of the Party to which it is affiliated and shall automatically terminate upon termination of the Access Rights granted to such Party.

Upon cessation of the status as an Affiliated Entity, any Access Rights granted to such former Affiliated Entity shall lapse.
Further arrangements with Affiliated Entities may be negotiated in separate agreements.

9.6 Additional Access Rights

For the avoidance of doubt any grant of Access Rights not covered by the Grant Agreement or this Consortium Agreement shall be at the absolute discretion of the owning Party and subject to such terms and conditions as may be agreed between the owning and receiving Parties.

9.7 Access Rights for Parties entering or leaving the consortium

9.7.1 New Parties entering the consortium

As regards Results developed before the accession of the new Party, the new Party will be granted Access Rights on the conditions applying for Access Rights to Background.

9.7.2 Parties leaving the consortium

9.7.2.1 Access Rights granted to a leaving Party

9.7.2.1.1 Defaulting Party

Access Rights granted to a Defaulting Party and such Party's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the Steering Committee to terminate its participation in the Consortium.

9.7.2.1.2 Non-defaulting Party

A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the Results developed until the date of the termination of its participation.

It may request Access Rights within the period of time specified in Section 9.4.3.

9.7.2.2 Access Rights to be granted by any leaving Party

Any Party leaving the Project shall continue to grant Access Rights pursuant to the Grant Agreement and this Consortium Agreement as if it had remained a Party for the whole duration of the Project.

10 Section: Non-disclosure of information

10.1

All information in whatever form or mode of communication, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") in connection with the Project during its implementation and which has been explicitly marked as "confidential" at the time of disclosure, or which is to be seen as confidential due to reasonably obvious circumstances, or when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 30 (thirty) calendar days from oral disclosure at the latest as confidential information by the Disclosing Party, is "Confidential Information".

10.2

The Recipients hereby undertake in addition and without prejudice to any commitment on non-disclosure under the Grand Agreement, for a period of 4 (four) years after the end of the Project:

- Not to use Confidential Information otherwise than for the purpose for which it was disclosed;
- not to disclose Confidential Information without the prior written consent by the Disclosing Party;
- to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
- to return to the Disclosing Party, or destroy, on request all Confidential Information that has been disclosed to the Recipients including all copies thereof and to delete all information stored in a machine readable form to the extent practically possible. The Recipients may keep a copy to the extent it is required to keep, archive or store such Confidential

Information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided that the Recipient comply with the confidentiality obligations herein contained with respect to such copy for as long as the copy is retained.

10.3

The recipients shall be responsible for the fulfilment of the above obligations on the part of their employees or third parties involved in the Project and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of the contractual relationship with the employee or third party.

10.4

The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

- the Confidential Information has become or becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
- the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
- the Confidential Information is communicated to the Recipient without any obligation of confidentiality by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidentiality to the Disclosing Party;
- the disclosure or communication of the Confidential Information is foreseen by provisions of the Grant Agreement;
- the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party;
- the Confidential Information was already known to the Recipient prior to disclosure, or
- the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section 10.7 hereunder (for example, by the obligation to publish the Consortium Agreement in the national register according to its applicable law).

10.5

The Recipient shall apply the same degree of care regarding the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care

10.6

Each Party shall promptly advise the other Party in writing of any unauthorized disclosure, misappropriation, or misuse of Confidential Information after it becomes aware of such unauthorized disclosure, misappropriation or misuse.

10.7

If any Party becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure

- notify the Disclosing Party, and
- comply with the Disclosing Party's reasonable instructions to protect the confidentiality of the information.

11 Section: Miscellaneous

11.1 Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and
Attachment 1 (Background included)
Attachment 2 (Accession document)
Attachment 3 (List of Third Parties for simplified transfer according to Section 8.5.2)
Attachment 4 (Identified Affiliated Entities)
Attachment 5 (Non-Disclosure Agreement for EAD members)
Attachment 6 (Data Transfer Agreement)

In case the terms of this Consortium Agreement are in conflict with the terms of the Grant Agreement, the terms of the latter shall prevail. In case of conflicts between the attachments and the core text of this Consortium Agreement, the latter shall prevail.

Should any provision of this Consortium Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Consortium Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated that fulfils the purpose of the original provision.

11.2 No representation, partnership or agency

Except as otherwise provided in Section 6.4.4, no Party shall be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

11.3 Notices and other communication

Any notice to be given under this Consortium Agreement shall be in writing to the addresses and recipients as listed in the most current address list kept by the Coordinator.

Formal notices:
If it is required in this Consortium Agreement (Sections 4.2, 9.7.2.1.1, and 11.4) that a formal notice, consent or approval shall be given, such notice shall be signed by an authorized representative of a Party and shall either be served personally or sent by mail with recorded delivery or telefax with receipt acknowledgement.

Other communication:
Other communication between the Parties may also be effected by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of written form.

Any change of persons or contact details shall be notified immediately by the respective Party to the Coordinator. The address list shall be accessible to all Parties.

11.4 Assignment and amendments

Except as set out in Section 8.5, no rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any third party without the other Parties' prior formal approval. Amendments and modifications to the text of this Consortium Agreement not explicitly listed in Section 6.3.5 require a separate written agreement to be signed between all Parties. For the avoidance of doubt, the Parties agree that the transmission of an electronic copy (e.g. scanned pdf) signed in wet ink as well as an electronic signature shall in any case be sufficient to comply with the agreed written form

requirement, being specified that each party will still have to send a paper version of the signed agreement or amendment.

11.5 Mandatory national law

Nothing in this Consortium Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

11.6 Language

This Consortium Agreement is drawn up in English, which language shall govern all documents, notices, meetings, arbitral proceedings and processes relative thereto. It is stated that the source documents are in language of the participating sites.

11.7 Applicable law

This Consortium Agreement shall be construed in accordance with and governed by the laws of Belgium excluding its conflict of law provisions.
The Clinical Trials will be executed by the participating sites under their respective national legislation.

11.8 Settlement of disputes

The parties shall endeavour to settle their disputes amicably.
In case of any dispute concerning the interpretation, performance, or validity of this Consortium Agreement, and except in emergencies that justify applying to a competent court for an injunction, the Parties will make every effort to settle out of court, possibly via the intermediary of the Steering Committee and their respective governing authorities.

If the Parties are unable to settle their dispute within three (3) months after it occurs, the case will be brought before the Belgium Courts with relevant jurisdiction by the prosecuting Party.

Nothing in this Consortium Agreement shall limit the Parties' right to seek injunctive relief in any applicable competent court.

12 Section Signatures

AS WITNESS:
The Parties have caused this Consortium Agreement to be duly signed by the undersigned authorized representatives in separate signature pages the day and year first above written.

Made in nine (9) copies

L'UNIVERSITE DE BORDEAUX

[redacted]
President
Date 26/02/2021

RHÖN-KLINIKUM CAMPUS BAD NEUSTADT

Management:

[redacted]

Date 25. Feb. 2021

[redacted]

Date 25. Feb. 2021

Head of electrophysiology:

[redacted]

Date [redacted]

26/2/2021

CHU HOPITAUX DE BORDEAUX

[redacted]
Managing Director
Date 25/02/2021

[redacted]

INSTITUT KLINICKÉ A EXPERIMENTÁLNÍ MEDÍCINY

[redacted]

Director

Date 26. 02. 2021

[redacted]

[redacted]

MEDIZINISCHE UNIVERSITAT GRAZ

[redacted]

Vice-Rector for Research and International Affairs

[redacted]

Head Dpt. of Inner Medicine

[redacted]

Read and acknowledged:

[redacted]

Project Lead

[redacted]

ALGEMEEN ZIEKENHUIS SINT-JAN BRUGGE-OOSTENDE AUTONOME VERZORGINSINSTELLING

[redacted]

General Director

Date 26/2/2021

[redacted]

Head of department of cardiology

25-2-21

[redacted]

Investigator

25/02/21

[redacted]

FARAPULSE INC

[redacted]

CFO and VP of Commercial Development and Business Operations

Date 25 FEBRUARY 2021

[redacted]

NEMOCNICE NA HOMOLCE [redacted]

[redacted]

MBA Director of Nemocnice Na Homolce

Date 26. 2. 2021 [redacted]

DEUTSCHES HERZZENTRUM MUNCHEN

[redacted]

Clinical Director

Date 26 - FEB - 2021

Attachment 1: Background included

According to the Grant Agreement (Article 24) Background is defined as “data, know-how or information (…) that is needed to implement the action or exploit the results”. Because of this need, Access Rights have to be granted in principle, but Parties must identify and agree amongst them on the Background for the project. This is the purpose of this attachment.

PARTY 1

As to **UNIVERSITÉ DE BORDEAUX**, it is agreed between the Parties that, to the best of their knowledge, no data, know-how or information of **UNIVERSITÉ DE BORDEAUX** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party’s Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 2

As to **RHÖN-KLINIKUM CAMPUS BAD NEUSTADT,** it is agreed between the Parties that, to the best of their knowledge no data, know-how or information of **RHÖN-KLINIKUM CAMPUS BAD NEUSTADT** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party’s Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 3

As to **CHU HOPITAUX DE BORDEAUX**, it is agreed between the Parties that, to the best of their knowledge no data, know-how or information of **CHU HOPITAUX DE BORDEAUX** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party’s Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 4

As to **INSTITUT KLINICKÉ A EXPERIMENTÁLNÍ MEDICINY**, it is agreed between the Parties that, to the best of their knowledge no data, know-how or information of **INSTITUT KLINICKÉ A EXPERIMENTÁLNÍ MEDICINY** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party’s Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 5

As to **MEDIZINISCHE UNIVERSITAT GRAZ**, it is agreed between the Parties that, to the best of their knowledge no data, know-how or information of **MEDIZINISCHE UNIVERSITAT GRAZ** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party’s Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

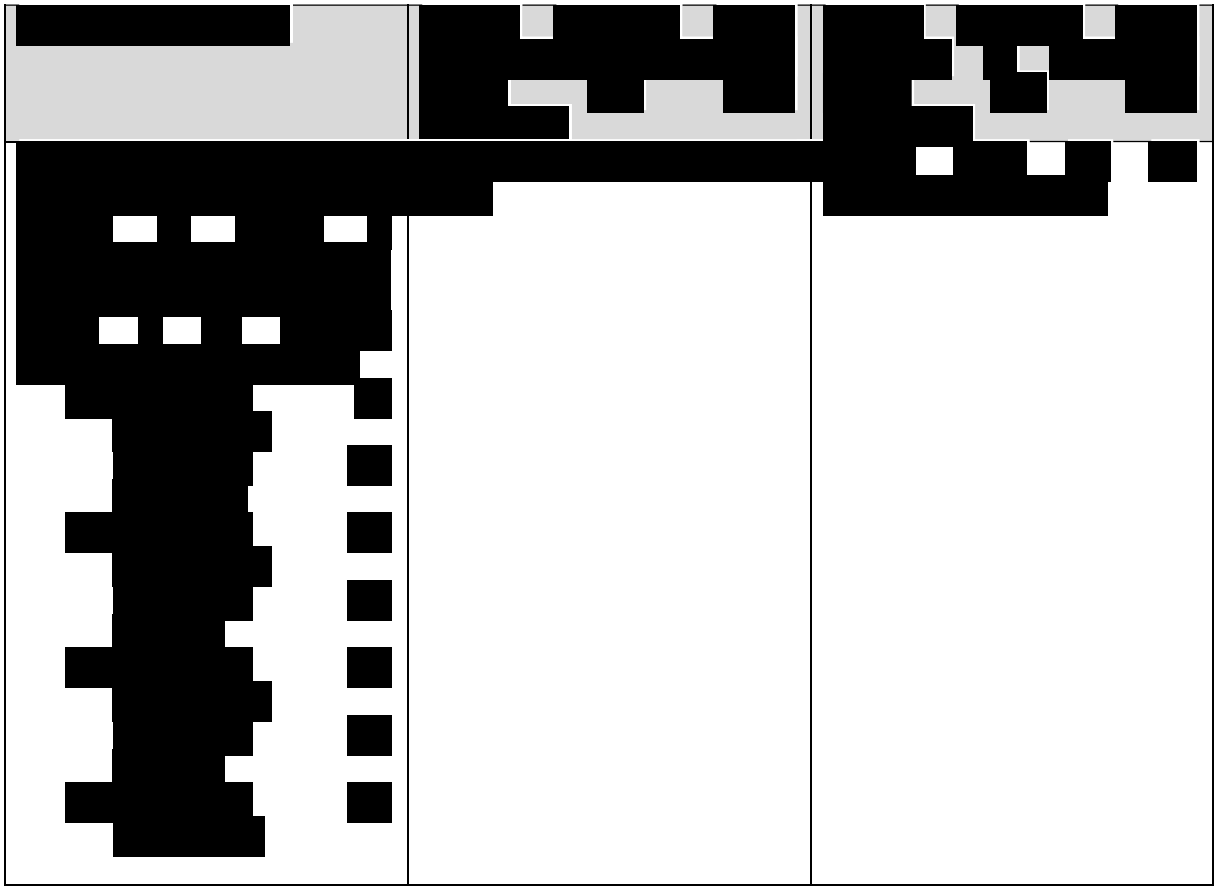
PARTY 6

As to **ALGEMEEN ZIEKENHUIS SINT-JAN BRUGGE-OOSTENDE AUTONOME VERZORGINSINSTELLING**, it is agreed between the Parties that, to the best of their knowledge no data, know-how or information of **ALGEMEEN ZIEKENHUIS SINT-JAN BRUGGE-OOSTENDE AUTONOME VERZORGINSINSTELLING** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 7

As to **FARAPULSE INC**, it is agreed between the Parties that, to the best of their knowledge the following background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:



represents the status at the time of signature of this Consortium Agreement.

PARTY 8

As to **NEMOCNICE NA HOMOLCE**, it is agreed between the Parties that, to the best of their knowledge no data, know-how or information of **NEMOCNICE NA HOMOLCE** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

PARTY 9

As to **DEUTSCHES HERZZENTRUM MUNCHEN**, it is agreed between the Parties that, to the best of their knowledge no data, know-how or information of **DEUTSCHES HERZZENTRUM MUNCHEN** shall be Needed by another Party for implementation of the Project (Article 25.2 Grant Agreement) or Exploitation of that other Party's Results (Article 25.3 Grant Agreement).

This represents the status at the time of signature of this Consortium Agreement.

Attachment 2: Accession document

ACCESSION

of a new Party to

[Acronym of the Project] Consortium Agreement, version […, YYYY-MM-DD]

[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE Grant Agreement]

hereby consents to become a Party to the Consortium Agreement identified above and accepts all the rights and obligations of a Party starting [date].

[OFFICIAL NAME OF THE COORDINATOR AS IDENTIFIED IN THE Grant Agreement]

hereby certifies that the consortium has accepted in the meeting held on [date] the accession of [the name of the new Party] to the consortium starting [date].

This Accession document has been done in 2 originals to be duly signed by the undersigned authorised representatives.

[Date and Place]

[INSERT NAME OF THE NEW PARTY]
Signature(s)
Name(s)
Title(s)

[Date and Place]

[INSERT NAME OF THE COORDINATOR]
Signature(s)
Name(s)
Title(s)

Attachment 3: List of Third Parties for simplified transfer according to Section 8.5.

None.

Attachment 4: Identified Affiliated Entities according to Section 9.5

For Université de Bordeaux: [redacted]

Attachment 5: Non-disclosure Agreement for EAB members

NON-DISCLOSURE AGREEMENT FOR EAB MEMBER

BETWEEN:

…
[Address],
Represented by [position], [Mr/Mrs/Ms]

Hereafter referred to as the "**EAB Member**",

on the first hand,

AND

…
[Address],
Represented by [position], [Mr/Mrs/Ms]

Hereafter referred to as "…",

on the second hand,

The Establishments and the EAB Member are referred to individually and jointly below as the "Party/Parties**".**

INTRODUCTION:

In the frame of the BEAT-AF project (hereafter referred to as the "Project"), an Ethics Advisory Board (EAB) is appointed to assist the decisions made by the Steering Committee of the Project.
The EAB will observe and deal with issues relevant to ethics. Functioning as an academic and patient-driven advisory group, it will evaluate and guide BEAT AF consortium on all ethics, patient safety and scientific conduct issues. The EAB will safeguard the project's compliance with all necessary ethical regulations by checking the ethical aspects of the study protocols and standards implemented for patient recruitment and prospective examinations.
In this context, the purpose of this Agreement is to establish rules concerning the protection and use of the Confidential Information that the Parties wish to exchange.

THE PARTIES HAVE AGREED TO THE FOLLOWING:

Article 1 – Definition

For the purposes of this contract, the following terms written with a capital letter have the following meanings:

Agreement: This confidentiality agreement between the Parties.

Confidential Information: any technical, commercial and strategic information in whatever form and/or material support exchanged between the Parties under this Consortium Agreement, including but not limited to this Consortium Agreement and its content, the fact that discussions are taking place on any transaction contemplated in this Consortium Agreement, and any analysis, notes or documents drafted or drawn up by a Party on the basis of or relating to the said technical, commercial and strategic information.

This information must be treated as confidential, whether or not the word "confidential" is used in the notes, studies, analyses, or any other document.

Article 2 – Purpose

The purpose of this Agreement is to establish rules concerning the protection and use of the Confidential Information that the Parties wish to exchange in the context defined in the Introduction.

Each of the Parties will transmit to the other Parties, on a non-exclusive basis, only the Confidential Information considered necessary to pursue the objectives of the Project. It is agreed that the disclosing Party does not provide any guarantees concerning the Confidential Information that they communicate to the other Party, particularly concerning their relevance to the Project.

No provision in this Agreement may be interpreted as obliging one of the Parties to transmit Confidential Information or to establish contractual relations with the others in the future.

Article 3 – Obligations of the Parties

The Parties which receive this Confidential Information agree that, throughout the term of the Agreement and for a period of five (5) years after its expiry or termination date, all Confidential Information from the originating Party:

a) will be protected, kept strictly confidential, and treated with the same care and protection as their own equally important Confidential Information, and not, in any case, less protectively;

b) will not be used, totally or partially, for other purpose other than those defined by the Agreement, as specified in the Introduction above, without the prior, written consent of the originating Party;

c) will not be communicated, nor is likely to be, either directly or indirectly, to any third parties or people other than those listed in article 5 below;

d) will not be copied, reproduced, or duplicated, totally or partially, unless the copies, reproductions, or duplications have been specifically authorised in writing by the originating Party.

Notwithstanding the provisions in articles 9 and 10 below, the expiry or termination of the Agreement will not release the Parties from their obligation to comply with the provisions of article 3 concerning the use and protection of the Confidential Information received before the termination or expiry date; the obligations in these provisions will remain in force during the period defined in the article concerned.

Article 4 - Exceptions

The Party receiving the Confidential Information will not be subject to any restrictions on their use, provided they can prove that:

a) it was already in the public domain prior to disclosure or released afterwards, without any negligence or fraud on their part; or

b) it was already known to them, as demonstrated by the existence of relevant documents in their files; or

c) it was received from a third party who was authorised to disclose it legally, without restriction or breach of the Agreement; or

d) its use or disclosure was authorised in writing by the originating Party; or

e) it was the result of internal developments, undertaken in good faith by members of staff who did not have access to this Confidential Information; or

f) its disclosure was required by law or court ruling, provided that, prior to disclosure, the Party required to transmit the Confidential Information informs the originating Party as soon as possible and takes any objection on their part into account.

Article 5 - Personnel

The Parties are only authorised to communicate the Confidential Information to members of their staff on a need-to-know basis for the needs of the Project.

Article 6 – Intellectual property

It is expressly agreed by the Parties that disclosure among themselves of Confidential Information under the Agreement cannot, in any case, be interpreted as expressly or implicitly granting any rights to the receiving Party (in terms of a licence or any other means) concerning the Confidential Information or any existing or future intellectual property or other rights to the Confidential Information.

All Confidential Information and media communicated and handed over by one Party are and will remain the exclusive property of that Party.

Article 7 - Restitution

7.1 If one Party decides to give up the Project, they agree to destroy or return, all the Confidential Information transmitted to them of their own accord, within eight (8) days.

7.2 If the Parties abandon the Project, all Confidential Information will be spontaneously destroyed or returned within eight (8) days, without keeping any copies, either on paper or a dematerialised medium.

7.3 On simple request from the originating Party, all Confidential information must be destroyed or returned within eight (8) days after the request. The destruction of the Confidential information must be confirmed to the originating Party in writing.

Article 8 – Confidentiality of the Agreement

The existence, content, and performance of this Agreement will be kept confidential by the Parties and will not be disclosed by either of them without the prior, written consent of the other Party/Parties.

Article 9 – Term

Notwithstanding the date it is signed, the Agreement will come into force on ____ for a period of XX. It shall not be renewed by tacit consent.
The Agreement may be renewed by an additional clause, drafted beforehand and signed by duly appointed representatives of the Parties.

Article 10 – Termination

The Agreement may be terminated by either of the Parties, at any time, automatically and without any formalities, by giving thirty (30) days' notice.

Article 11 – Miscellaneous provisions

Entirety of the Agreement: The provisions of this Agreement constitute the entirety of the agreement between the Parties. It cancels and replaces any written or verbal agreements between the Parties prior to its signature.

Assignment: The Agreement may not be assigned or transferred by a Party to a third party, in full or in part, by any means whatsoever, without the prior, written consent of the other Party/Parties.

Modification: The Agreement may only be amended or modified by an additional clause signed by duly authorised representatives of each Party.

Nullity of a clause: If one or more of the provisions in the Agreement are considered invalid or declared invalid in application of a treaty, law, or regulation, or by a judicial ruling, the other provisions will retain their full force and scope.

Tolerance: The Parties agree reciprocally that the fact that one of them tolerates a situation does not automatically grant any rights to the other Party/Parties. This tolerance shall not be interpreted as a waiver of the the rights concerned.

Article 12 – Applicable law – Disputes

12.1 The Agreement is governed by Belgium law

12.2 Any disputes between the Parties concerning the existence, validity, interpretation, performance, or termination of the Agreement that the Parties are not able to settle among themselves will be brought before the Courts with relevant jurisdiction.

Two (2) copies signed in Bordeaux.

[INSERT NAME OF PARTY]

Signature(s)

Name(s)

Title(s)

Date

[INSERT NAME OF PARTY]
Signature(s)
Name(s)
Title(s)
Date

Attachment 6: Data Transfer Agreement

Standard contractual clauses for the transfer of personal data from the Community to third countries (controller to controller transfers)

Data transfer agreement

between

The Sponsor – France (EU)

hereinafter “data exporter”)

and

FARAPULSE– USA

hereinafter “data importer”

each a “party”; together “the parties”.

Definitions

For the purposes of the clauses:

(a)“personal data”, “special categories of data/sensitive data”, “process/processing”, “controller”, “processor”, “data subject” and “supervisory authority/authority” shall have the same meaning as in Directive 95/46/EC of 24 October 1995 (whereby “the authority” shall mean the competent data protection authority in the territory in which the data exporter is established);

(b) “the data exporter” shall mean the controller who transfers the personal data;

(c)“the data importer” shall mean the controller who agrees to receive from the data exporter personal data for further processing in accordance with the terms of these clauses and who is not subject to a third country’s system ensuring adequate protection;

(d)“clauses” shall mean these contractual clauses, which are a free-standing document that does not incorporate commercial business terms established by the parties under separate commercial arrangements.

The details of the transfer (as well as the personal data covered) are specified in Annex B, which forms an integral part of the clauses.

I. Obligations of the data exporter

The data exporter warrants and undertakes that:

(a)The personal data have been collected, processed and transferred in accordance with the laws applicable to the data exporter.

(b)It has used reasonable efforts to determine that the data importer is able to satisfy its legal obligations under these clauses.

(c)It will provide the data importer, when so requested, with copies of relevant data protection laws or references to them (where relevant, and not including legal advice) of the country in which the data exporter is established.

(d)It will respond to enquiries from data subjects and the authority concerning processing of the personal data by the data importer, unless the parties have agreed that the data importer

will so respond, in which case the data exporter will still respond to the extent reasonably possible and with the information reasonably available to it if the data importer is unwilling or unable to respond. Responses will be made within a reasonable time.

(e) It will make available, upon request, a copy of the clauses to data subjects who are third party beneficiaries under clause III, unless the clauses contain confidential information, in which case it may remove such information. Where information is removed, the data exporter shall inform data subjects in writing of the reason for removal and of their right to draw the removal to the attention of the authority. However, the data exporter shall abide by a decision of the authority regarding access to the full text of the clauses by data subjects, as long as data subjects have agreed to respect the confidentiality of the confidential information removed. The data exporter shall also provide a copy of the clauses to the authority where required.

II. Obligations of the data importer

The data importer warrants and undertakes that:

(a) It will have in place appropriate technical and organisational measures to protect the personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, and which provide a level of security appropriate to the risk represented by the processing and the nature of the data to be protected.

(b) It will have in place procedures so that any third party it authorises to have access to the personal data, including processors, will respect and maintain the confidentiality and security of the personal data. Any person acting under the authority of the data importer, including a data processor, shall be obligated to process the personal data only on instructions from the data importer. This provision does not apply to persons authorised or required by law or regulation to have access to the personal data.

(c) It has no reason to believe, at the time of entering into these clauses, in the existence of any local laws that would have a substantial adverse effect on the guarantees provided for under these clauses, and it will inform the data exporter (which will pass such notification on to the authority where required) if it becomes aware of any such laws.

(d) It will process the personal data for purposes described in Annex B, and has the legal authority to give the warranties and fulfil the undertakings set out in these clauses.

(e) It will identify to the data exporter a contact point within its organisation authorised to respond to enquiries concerning processing of the personal data, and will cooperate in good faith with the data exporter, the data subject and the authority concerning all such enquiries within a reasonable time. In case of legal dissolution of the data exporter, or if the parties have so agreed, the data importer will assume responsibility for compliance with the provisions of clause I(e).

(f) At the request of the data exporter, it will provide the data exporter with evidence of financial resources sufficient to fulfil its responsibilities under clause III (which may include insurance coverage).

(g) Upon reasonable request of the data exporter, it will submit its data processing facilities, data files and documentation needed for processing to reviewing, auditing and/or certifying by the data exporter (or any independent or impartial inspection agents or auditors, selected by the data exporter and not reasonably objected to by the data importer) to ascertain compliance with the warranties and undertakings in these clauses, with reasonable notice and during regular business hours. The request will be subject to any necessary consent or approval from a regulatory or supervisory authority within the country of the data importer, which consent or approval the data importer will attempt to obtain in a timely fashion.

(h) It will process the personal data, at its option, in accordance with:

(i) the data protection laws of the country in which the data exporter is established, or

(ii) the relevant provisions of any Commission decision pursuant to Article 25(6) of Directive 95/46/EC, where the data importer complies with the relevant provisions of such an authorisation or decision and is based in a country to which such an authorisation or decision pertains, but is not covered by such authorisation or decision for the purposes of the transfer(s) of the personal data, or

(iii) the data processing principles set forth in Annex A.

Data importer to indicate which option it selects:

Initials of data importer:__;

(i) It will not disclose or transfer the personal data to a third party data controller located outside the European Economic Area (EEA) unless it notifies the data exporter about the transfer and

(i) the third party data controller processes the personal data in accordance with a Commission decision finding that a third country provides adequate protection, or

(ii) the third party data controller becomes a signatory to these clauses or another data transfer agreement approved by a competent authority in the EU, or

(iii) data subjects have been given the opportunity to object, after having been informed of the purposes of the transfer, the categories of recipients and the fact that the countries to which data is exported may have different data protection standards, or

(iv) with regard to onward transfers of sensitive data, data subjects have given their unambiguous consent to the onward transfer

III. Liability and third party rights

(a) Each party shall be liable to the other parties for damages it causes by any breach of these clauses. Liability as between the parties is limited to actual damage suffered. Punitive damages (i.e. damages intended to punish a party for its outrageous conduct) are specifically excluded. Each party shall be liable to data subjects for damages it causes by any breach of third party rights under these clauses. This does not affect the liability of the data exporter under its data protection law.

(b) The parties agree that a data subject shall have the right to enforce as a third party beneficiary this clause and clauses I(b), I(d), I(e), II(a), II(c), II(d), II(e), II(h), II(i), III(a), V, VI(d) and VII against the data importer or the data exporter, for their respective breach of their contractual obligations, with regard to his personal data, and accept jurisdiction for this purpose in the data exporter's country of establishment. In cases involving allegations of breach by the data importer, the data subject must first request the data exporter to take appropriate action to enforce his rights against the data importer; if the data exporter does not take such action within a reasonable period (which under normal circumstances would be one month), the data subject may then enforce his rights against the data importer directly. A data subject is entitled to proceed directly against a data exporter that has failed to use reasonable efforts to determine that the data importer is able to satisfy its legal obligations under these clauses (the data exporter shall have the burden to prove that it took reasonable efforts).

IV. Law applicable to the clauses

These clauses shall be governed by the law of the country in which the data exporter is established, with the exception of the laws and regulations relating to processing of the personal data by the data importer under clause II(h), which shall apply only if so selected by the data importer under that clause.

V. Resolution of disputes with data subjects or the authority

(a) In the event of a dispute or claim brought by a data subject or the authority concerning the processing of the personal data against either or both of the parties, the parties will inform each other about any such disputes or claims, and will cooperate with a view to settling them amicably in a timely fashion.

(b) The parties agree to respond to any generally available non-binding mediation procedure initiated by a data subject or by the authority. If they do participate in the proceedings, the parties may elect to do so remotely (such as by telephone or other electronic means). The parties also agree to consider participating in any other arbitration, mediation or other dispute resolution proceedings developed for data protection disputes.

(c) Each party shall abide by a decision of a competent court of the data exporter's country of establishment or of the authority which is final and against which no further appeal is possible.

VI. Termination

(a) In the event that the data importer is in breach of its obligations under these clauses, then the data exporter may temporarily suspend the transfer of personal data to the data importer until the breach is repaired or the contract is terminated.

(b) In the event that:

(i) the transfer of personal data to the data importer has been temporarily suspended by the data exporter for longer than one month pursuant to paragraph (a);

(ii) compliance by the data importer with these clauses would put it in breach of its legal or regulatory obligations in the country of import;

(iii) the data importer is in substantial or persistent breach of any warranties or undertakings given by it under these clauses;

(iv) a final decision against which no further appeal is possible of a competent court of the data exporter's country of establishment or of the authority rules that there has been a breach of the clauses by the data importer or the data exporter; or

(v) a petition is presented for the administration or winding up of the data importer, whether in its personal or business capacity, which petition is not dismissed within the applicable period for such dismissal under applicable law; a winding up order is made; a receiver is appointed over any of its assets; a trustee in bankruptcy is appointed, if the data importer is an individual; a company voluntary arrangement is commenced by it; or any equivalent event in any jurisdiction occurs

then the data exporter, without prejudice to any other rights which it may have against the data importer, shall be entitled to terminate these clauses, in which case the authority shall be informed where required. In cases covered by (i), (ii), or (iv) above the data importer may also terminate these clauses.

(c) Either party may terminate these clauses if (i) any Commission positive adequacy decision under Article 25(6) of Directive 95/46/EC (or any superseding text) is issued in relation to the country (or a sector thereof) to which the data is transferred and processed by the data

importer, or (ii) Directive 95/46/EC (or any superseding text) becomes directly applicable in such country.

(d) The parties agree that the termination of these clauses at any time, in any circumstances and for whatever reason (except for termination under clause VI(c)) does not exempt them from the obligations and/or conditions under the clauses as regards the processing of the personal data transferred.

VII. Variation of these clauses

The parties may not modify these clauses except to update any information in Annex B, in which case they will inform the authority where required. This does not preclude the parties from adding additional commercial clauses where required.

VIII. Description of the Transfer

The details of the transfer and of the personal data are specified in Annex B. The parties agree that Annex B may contain confidential business information which they will not disclose to third parties, except as required by law or in response to a competent regulatory or government agency, or as required under clause I(e). The parties may execute additional annexes to cover additional transfers, which will be submitted to the authority where required. Annex B may, in the alternative, be drafted to cover multiple transfers.

Dated:

FOR DATA IMPORTER **FOR DATA EXPORTER**

ANNEX A

DATA PROCESSING PRINCIPLES

1. Purpose limitation: Personal data may be processed and subsequently used or further communicated only for purposes described in Annex B or subsequently authorised by the data subject.
2. Data quality and proportionality: Personal data must be accurate and, where necessary, kept up to date. The personal data must be adequate, relevant and not excessive in relation to the purposes for which they are transferred and further processed.
3. Transparency: Data subjects must be provided with information necessary to ensure fair processing (such as information about the purposes of processing and about the transfer), unless such information has already been given by the data exporter.
4. Security and confidentiality: Technical and organisational security measures must be taken by the data controller that are appropriate to the risks, such as against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, presented by the processing. Any person acting under the authority of the data controller, including a processor, must not process the data except on instructions from the data controller.
5. Rights of access, rectification, deletion and objection: As provided in Article 12 of Directive 95/46/EC, data subjects must, whether directly or via a third party, be provided with the personal information about them that an organisation holds, except for requests which are manifestly abusive, based on unreasonable intervals or their number or repetitive or systematic nature, or for which access need not be granted under the law of the country of the data exporter. Provided that the authority has given its prior approval, access need also not be granted when doing so would be likely to seriously harm the interests of the data importer or other organisations dealing with the data importer and such interests are not overridden by the interests for fundamental rights and freedoms of the data subject. The sources of the personal data need not be identified when this is not possible by reasonable efforts, or where the rights of persons other than the individual would be violated. Data subjects must be able to have the personal information about them rectified, amended, or deleted where it is inaccurate or processed against these principles. If there are compelling grounds to doubt the legitimacy of the request, the organisation may require further justifications before proceeding to rectification, amendment or deletion. Notification of any rectification, amendment or deletion to third parties to whom the data have been disclosed need not be made when this involves a disproportionate effort. A data subject must also be able to object to the processing of the personal data relating to him if there are compelling legitimate grounds relating to his particular situation. The burden of proof for any refusal rests on the data importer, and the data subject may always challenge a refusal before the authority.
6. Sensitive data: The data importer shall take such additional measures (e.g. relating to security) as are necessary to protect such sensitive data in accordance with its obligations under clause II.
7. Data used for marketing purposes: Where data are processed for the purposes of direct marketing, effective procedures should exist allowing the data subject at any time to “opt-out” from having his data used for such purposes.
8. Automated decisions: For purposes hereof “automated decision” shall mean a decision by the data exporter or the data importer which produces legal effects concerning a data subject or significantly affects a data subject and which is based solely on automated processing of personal data intended to evaluate certain personal aspects relating to him, such as his

performance at work, creditworthiness, reliability, conduct, etc. The data importer shall not make any automated decisions concerning data subjects, except when:

(a)(i)such decisions are made by the data importer in entering into or performing a contract with the data subject, and

(ii)(the data subject is given an opportunity to discuss the results of a relevant automated decision with a representative of the parties making such decision or otherwise to make representations to that parties.

Or

(b) where otherwise provided by the law of the data exporter.

ANNEX B - DESCRIPTION OF THE TRANSFER

Data subjects:

The personal data transferred concern the following categories of data subjects:

- Patients including in study
- Health professionals participating at study

Purposes of the transfer(s):

The transfer is made for the following purpose:

- Quality assurance of research
- Safety reporting
- Internal development and regulatory purposes

Categories of data:

The personal data transferred concern the following categories of data:

Data categories	Type of Data Subjects	
	Professional contacts	Patients
Direct Identification data (e.g. name, surname, date of birth)	Yes	Yes (limited*)
Indirect Identification data (eg. code)	No	Yes
Contact data (e.g. address, phone, e-mail etc…)	Yes (professional)	No
Technical data (e.g. IP address, event logs)	Yes	No
Professional data (e.g. qualification & training, including in a form of curriculum vitae(s)	Yes	No
Data conveying information about personal life (e.g. quality of life questionnaires, potentially including questions about sex life, etc…)	No	Yes
Data conveying information about origins (e.g. ethnicity etc…)	No	Yes
Health data (e.g. disease, treatments, health images etc…)	No	Yes
Genetic data (e.g. somatic or germ line mutations etc…)	No	Yes

*Collection of identification data related to patients is limited to the date of birth (only if allowed by the national law); otherwise the access to fully identifiable information is possible only in the scope of the On-site only for the source data verification.

Recipients:

The personal data transferred may be disclosed only to the following recipients of categories of recipients:

Persons mandated by the data importer and subject to the obligations of confidentiality and professional secret.

Sensitive data:

The personal data transferred concern the following categories of sensitive data:

Genetic data, data concerning health and data concerning a natural person's sex life.

Data protection registration information of data exporter:

Registration in the register file.

Additional useful information (storage limits and other relevant information):

Contacts points for data protection enquiries:

[redacted]

Data exporter: [redacted]