MULTI-CENTRE, ADAPTIVE, RANDOMIZED TRIAL OF THE SAFETY AND EFFICACY OF TREATMENTS OF COVID-19 IN HOSPITALIZED ADULTS
PROTOCOL NO.20-15

CLINICAL TRIAL AGREEMENT

C5440

Between

The French National Institute for Health and Medical Research (*Institut National de la Santé et de la Recherche Médicale,* "Inserm"),
a public scientific and technological institute, located at 101 rue de Tolbiac, 75013 Paris, France (mailing address: 101 rue de Tolbiac, 75654 Paris cedex 13), VAT no. FR 31180036048,
represented by its Chairman and General Manager, xxxxxxxxxx,

hereinafter "Sponsor"

AND

Fakultní nemocnicí u sv. Anny v Brně,
state subsidized organization, located at Pekařská 53, 656 91 Brno, Czech Republic, Company ID: 00159816, VAT ID: CZ00159816,
represented by its Director Ing. Vlastimil Vajdák

Hereinafter "Site"

Hereinafter each referred to individually as a "Party" and collectively as the "Parties".

WHEREAS the Sponsor is Inserm, which is a public research organization dedicated to Human Health;
Since march 22 2020, Inserm is implementing a research that involves the participation of human subjects in several countries, entitled "*Multi-centre, adaptive, randomized trial of the safety and efficacy of treatments of COVID-19 in hospitalized adults*", protocol NO.C 20-15, referenced under the acronym DisCoVeRy and under reference C20-15, in which several products were and are used. For the performance of this clinical trial, Inserm entered into and will have to enter into agreements with industrial partners for the supplying of the products.

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

The WorkPackage n°1 of this proposal and of the Study is the continuation of the clinical trial DisCoVeRy sponsored by Inserm since March 22,2020.

With a Consortium Agreement, Inserm will specify or supplement binding commitments in addition to the provisions of the specific Grant Agreement ("hereinafter "Grant Agreement").

Separate agreements will be concluded by and between the Sponsor and the concerned parties and as the case may be, third parties involved in the Study to specify the terms and conditions for performance of the said Study.

In light of the global health situation caused by the Coronavirus, Inserm agrees on the conclusion and signature of this Clinical Trial Agreement, to be amended, prior the signature of the currently under review Consortium Agreement. The Sponsor shall ensure that the provisions of the current Agreement are not in discrepancy with the provisions of the Consortium Agreement.

ARTICLE 1. DEFINITIONS

For the purposes of interpretation and execution of the present Agreement, the Parties accept and recognize that each of the terms hereinafter shall always have the significance, which is defined as follows subject to explicit and written exception. Definitions in the singular form shall include the plural and vice versa.

The following words and phrases have the following meanings:

Agent(s)	Includes, but shall not be limited to, any person undertaking a function in connection with this Agreement (including the Principal Investigator, any nurse or other health professional), any such person's principal employer in the event it is not the Parties and where such person is providing services to a Party under a contract for services or otherwise (including clinical academics), and/or any contracted third party providing services to a Party under a contract for services or otherwise.
Agreement	This current agreement, together with the APPENDIX annexed hereto.
Authorisations	Means all notices and authorisations delivered by the Competent Authorities prior to conducting the Study whose deliverance is necessary for implementation of the Study in a Country
Competent Authorities	Means all authorities of the Country with which formalities must be carried out prior to conducting the Study, in accordance with the laws and regulations in force and effect in the Country where the Study shall take place.
Country	Means the country where the Study is conducted
Chief Investigator or CI	The person who takes overall responsibility for the design, conduct and reporting of the Study or if a multi-site Study, the person who takes primary responsibility for the design, conduct and reporting of the entire multi-site Study, whether or not the person is a Principal Investigator at any particular Site.
Clinical Data	Any data related to a specific Participant (personal data such as defined in Article 4.1 of GDPR) which may include, without limitation, medical records, medical imaging data, scans, questionnaires, readouts of individual biomedical or genetic analysis.
Confidential Information	Means any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed.
Controller	Shall have the meaning set out in the Data Protection Legislation, especially in the Article 4.7 of the GDPR

Data	Data means data which is either owned/stored by a Party before the commencement of the Study or which is generated under the Study. Data may be Personal Data within the meaning of the Regulation 2016/679 of 14 April 2016 and shall include as well Clinical Data and Study Data.
Data Protection Legislation	All applicable data protection and privacy legislation, regulations and guidance including but not limited to Regulation (EU) 2016/679 (the "General Data Protection Regulation" or "GDPR"), the time).
Data Subject	As defined in the Data Protection Legislation. The notion of Participant is included in the notion of Data Subject. However, the notion of Data Subject can be wider than the notion of Participant.
Intellectual Property Rights	As set forth in the Article 2 of the Convention establishing the World Intellectual Property Organisation, signed at Stockholm on 17 July 1967.
Intervention	In the case of other research projects, the intervention that is to be investigated as specified in the Protocol.
Clinical Trial Unit	A research unit that can help the Sponsor to coordinate clinical trials in the Country.
Participant	Any person who consents (where consent is necessary) and is enrolled to take part in the Study. All references to Participants in this Agreement refer to those recruited by or through the Site.
Parties	The contracting body for the Site.
Principal Investigator or PI	The leader responsible for a team of individuals conducting the Study at the Site and who has signed the declaration at APPENDIX 5
Pharmaceutical Provider	Means the service provider appointed by the Sponsor. Pharmaceutical Provider will be in particular in charge of the Products, packaging, labelling and sending to the pharmacies of the Sites. The Sponsor shall be the sole responsible in the identification of the Pharmaceutical Provider.
Process	As defined in the Data Protection Legislation (and "Process" and "Processed" shall be construed accordingly), especially the Article 4.2 of the GDPR
Processor	Shall have the meaning as set out in the Data Protection Legislation, especially the Article 4.8 of the GDPR
Product	The investigational medicinal product (IMP) / investigational medicinal product/s (IMPs) specified in the Protocol (including, where applicable, placebo).

Protocol	The full description of the Study with the reference number set out on the front page of this Agreement, together with any amendments thereof, and incorporated into this Agreement by reference.
Results	Results means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the Study, as well as any rights attached to it, including intellectual property rights. Results do not include any sideground, defined as tangible or intangible output generated by a Party under the action, such as data, knowledge and information whatever their form or nature, whether or not they can be protected, but which are outside of the Study objectives as defined in this Agreement and which therefore are not needed for implementing the action or for research use of results. Results do not include any background from Parties, defined as tangible or intangible output generated by a Party under the Study, such as data, knowledge and information whatever their form or nature, whether or not they can be protected, but which are held by the Parties priori to their accession to this Agreement. Each Party remains the exclusive owner of its background and sideground.
Sample	Any clinical biological sample or portion thereof, derived from Participants, including any information related to such material, supplied by the Parties to the Sponsor or its nominee.
Site	Any premises occupied by the Parties in which or through which the Study will be conducted.
Sponsor	Means the Party who takes responsibility for the initiation, management and financing (or arranging of financing) of the Study, and the regulatory responsibilities which accompany the role.
Study	Means the Study entitled “MULTI-CENTRE, ADAPTIVE, RANDOMIZED TRIAL OF THE SAFETY AND EFFICACY OF TREATMENTS OF COVID-19 IN HOSPITALIZED ADULTS PROTOCOL NO.20-15”
Study Data	All discoveries, data, information, theories, methods, computer programmes, format of presentations and applications of the same and all manifestations or expressions of the same in physical, chemical, biological, molecular, electronic or written form arising from the performance of the Study.
Tasks	Means roles and responsibilities of a Party under this Agreement in relation to the Study

The Research Laboratories	Means research laboratories involved in the Study where the samples will be centralized and analysed as described in the Protocol.
Study Monitor	Person in charge of the monitoring of the Study. His responsibilities are detailed in the monitoring plan.

Any reference to a statutory provision, code or guidance shall be deemed to include reference to any subsequent modification or re-enactment of it.

ARTICLE 2. OBLIGATIONS OF THE PARTIES

2.1

The Parties agree to comply with all relevant laws, regulations and codes of practice applicable in Czech Republic to this Agreement including to the performance of the Study. The Parties agree to comply with the World Medical Association Declaration of Helsinki, titled “Ethical Principles for Medical Research Involving Human Subjects” and the 2001/20/EC Clinical Trials Directive.

The Parties shall conduct the Study in accordance with:

- the Protocol and any amendment approved by the relevant ethics committee.
- the terms of all relevant regulatory permissions and approvals. These may include, but are not limited to:
    - the Authorisations granted by the Country Competent Authority (the "NCA");
    - the Authorisations granted by the relevant ethics committee;
    - the ICH GCP E6 (R2);
    - Good Manufacturing Practices (GMP);
    - Good Vigilance Practices (GVP);

2.2

The Parties shall carry out their respective responsibilities in accordance with this Agreement. The Site shall appoint a Principal Investigator who will be responsible for the research at Site and who has signed the declaration at APPENDIX 5.

2.3

The Study may only be initiated once favorable report from an Ethical Committee of the national territory, local Ethical Committee and the approval of the National Competent Authority are issued and will have an estimated duration xxx.
The Study will be carried out with an estimated number of xxx Participants and in a recruitment period of xxx, as detailed in the Protocol; said number and term may be modified when deemed necessary upon prior approval of the relevant budget. An estimated number of xxx Participants will be randomised by the Site.

2.4

Development and management of the Protocol and proposal of amendments shall be approved by the Sponsor and Authorities. This validation may require a prior meeting of the

Trial Steering Committee. The Parties agree that enrolment in the Study in any given Country will not start until (1) the version of the Protocol to be used has been reviewed and accepted and, as the case may be, signed by the Coordinating Investigator, the Sponsor and (2) the Authorisation shall be provided by the National Authorities. The Parties agree that any alteration in or amendment to the Protocol must be reviewed in advance by the project management team, and approved in writing by the relevant Authorities. The Protocol must meet all applicable laws or regulations. For the avoidance of doubt, each Party agrees the Protocol shall be a master document used in each Country, subject to the local adjustments in accordance with the laws and regulation in force in the Country.

2.5

In order to avoid any conflict of interest, the Site hereby agrees to cooperate with the Sponsor and the Site shall inform the Sponsor without delay if it intends to take up a research project with a third party that might cover or affect the performance of its Tasks in whole or in part. The Parties confirm that neither it, its employees or Agents including the Investigator and designate(s) nor its collaborators have any obligations with any third party, and that no third party has any rights, that might be in conflict with the obligations under this Agreement, and that neither the Parties, its employees or Agents including the Investigator and designate(s) nor its collaborators will enter into any such agreements during the term hereof without the prior written consent of the Sponsor.

2.6

The Sponsor shall, on the giving of reasonable prior written notice to the Site, have the right to audit the Site compliance with this Agreement. The Sponsor may appoint an auditor to carry out such an audit. Such right to audit shall include access, during normal working hours to the Site premises and to all relevant documents and other information relating to the Study.

Sponsor is obligated to inform the Site through the Department of Clinical Trials about planned date of initiation visit and termination visit, an audit and about date of enrollment beginning and enrollment closure via e-mail xxxxxxxxxx. Sponsor is obligated to conduct the visits mentioned above during usual working hours of the Institution after a mutual agreement with the Investigator, or an authorized employee of the Site. The Sponsor agrees that, in addition to the Investigator, other authorized employees of the Site will participate in these visits, if necessary.

2.7

The Site shall;

- promptly notify the Sponsor should any responsible body, such as, but not limited to, the NCA, conduct or give notice of intent to conduct any inspection at the Parties in relation to the Study;
- allow the Sponsor to support the preparations for such inspection; and
- following the inspection, provide the Sponsor with the results of the inspection relevant to the Study.

2.8

The Sponsor shall inform the Site and the Principal Investigator of the name and telephone number of the Study Monitor and the name of the person who will be available as a point of contact.

2.9

The Site agrees to ensure that the trial participants shall not participate in the Study until after they sign their informed consent provided by the Sponsor. Informed consent will include consent to inclusion in the Study as well as consent to the processing of personal data of Study Participants.

2.10

In accordance with Participant consent, the Parties shall permit the Sponsor's appointed representatives and any appropriately appointed monitor access to all relevant Clinical Data for monitoring, source data verification and adverse event reporting or investigation as appropriate, including without limitation source documentation and data contained in laboratory notebooks. The Parties agree that such access will be arranged at mutually convenient times and on reasonable notice according to article 2.5. Such monitoring may take such form as the Sponsor reasonably thinks appropriate including the right to inspect any facility being used for the conduct of the Study, reasonable access to relevant members of staff at the Parties the right to examine any procedures or records relating to the Study. The Sponsor will alert the Parties promptly to significant issues (in the opinion of the Sponsor) relating to the conduct of the Study.

2.11

The Parties shall ensure that the Principal Investigator, Sub-Investigators and any Sub-Investigators joining the Study following the initiation of the Trial, undertake any such appropriate training as the Sponsor may consider necessary for the conduct of the Study, including but not limited to the training and provision of information given during Investigator Meetings. Any and all training should be documented and filed appropriately.

2.12

The Site shall ensure that data shall be collected and entered within 7 days in the electronic case report forms (hereinafter referred to as "CRF") in accordance with the requirements set forth in the Protocol. When a Data Safety Monitoring Board is planned, data shall be collected and entered within 48 hours in the CRF. The Site agrees to assist in promptly clarifying and answering any questions concerning CRF data.

ARTICLE 3. LIABILITIES AND INDEMNITY

In accordance with Applicable Laws, the Sponsor shall assume, even without fault, the responsibility for any damage incurred by a Participant or, in the case of death, his rightful claimants, that arises either in direct or indirect connection with the Study and shall provide compensation therefore.

The Sponsor will take out and maintain in full force and effect through the performance of the Study (and following termination of the Study to cover any claims arising from the Study) appropriate insurance cover required by Article 52 para. 3 (f) of Act No. 378/2007 Coll., on Medicinal Products (as amended) or will provide an indemnity satisfactory to the Parties in respect of its potential liability under this article 3. An evidence of the insurance coverage taken out, upon the signing of the contract, is annexed (see. APPENDIX 4).

Nothing in this article 3 shall operate so as to restrict or exclude the liability of a Party in relation to statutory or regulatory liability (including but not limited to breach of the Data Protection Legislation), death or personal injury caused by the negligence or wilful misconduct of that Party or its Agent(s), fraud or fraudulent misrepresentation or to restrict or exclude any other liability of a Party which cannot be so restricted or excluded in law.

The Site warrants that in conformance with § 45 (2) (n) of the Act No. 372/2011 Coll., on Health Services and conditions of their provision, as amended, the Site concluded an insurance policy for the liability insurance for damage caused by the provision of health care; this insurance policy is concluded in the extent required by the law and does not include liability insurance for the damage caused by the conduct of the Study.

The Sponsor holds harmless the Parties, its employees and Agents, including the Investigator and designate(s), against all claims and proceedings (to include any settlements or ex gratia payments made with the consent of the parties hereto and reasonable legal and expert costs and expenses) made or brought (whether successfully or otherwise):

- by or on behalf of Participants taking part in the Study (or their dependents) against the Parties, its employees or Agents including the Investigators and designate(s) for personal injury (including death) to Participants arising out of or relating to the administration of the Product(s) under investigation or any clinical intervention or procedure provided for or required by the Protocol to which the Participants would not have been exposed but for their participation in the Study;
- by the Parties, its employees or Agents including the Investigator and designate(s) or on behalf of a Participant (or his dependants) for a declaration concerning the treatment of a Participant who has suffered such personal injury.

The above stipulation shall not apply to any such claim or proceeding:

- to the extent that such personal injury (including death) is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Parties, its employees or Agents including the Investigator and designate(s);
- to the extent that such personal injury (including death) is caused by the failure of the Parties, its employees or Agents including the Investigator and designate(s) to conduct the Study in accordance with the Protocol;
- unless as soon as reasonably practicable following receipt of notice of such claim or proceeding, the Parties shall have notified the Sponsor in writing of it and shall, upon the Sponsor's request, and at the Sponsor's cost, have permitted the Sponsor to participate in the settlement of the claim or proceeding using legal representation of its own choosing;
- if the Parties, its employees or Agents including the Investigator and designate(s) shall have made any admission in respect of such claim or proceeding or taken any action relating to such claim or proceeding prejudicial to the defence of it without the prior written consent of the Sponsor such consent not to be unreasonably withheld; provided that this condition shall not be treated as breached by a statement properly made by the Parties, its employees or Agents including the Investigator and designate(s), where such statement is required by law or where the content and publication of such statement has been agreed by the Parties and the Sponsor.

The Sponsor shall keep the Parties and its legal advisers fully informed of the progress of any such claim or proceeding, will notify the Parties of the nature of any defence to be advanced and will not settle any such claim or proceeding without notification to the Parties.

Without prejudice to the provisions of the paragraphs above, the Parties will use its reasonable endeavours to inform the Sponsor promptly of any circumstances reasonably thought likely to give rise to any such claim or proceeding of which it is aware and shall keep the Sponsor reasonably informed of developments in relation to any such claim or proceeding. Likewise the Sponsor shall use its reasonable endeavours to inform the Parties of any such circumstances and shall keep the Parties reasonably informed of developments in relation to any such claim or proceeding made or brought against the Sponsor in connection with the Study.

- The Party and the Sponsor will each give to the other such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding by or on behalf of Subjects (or their dependants) or concerning such a declaration as is referred to in the paragraphs above.
- The Party is entitled to rely fully upon the accuracy of all information supplied to it by or on behalf of the Sponsor concerning the drugs under study and is not required to obtain independent verification of any information supplied.

The Sponsor is not entitled to admit the fault of the Site or the Investigator without the prior written consent of the Site when settling the claims of third parties.

ARTICLE 4. PRODUCT SUPPLY AND USE

4.1 Supply, Distribution and Use of the Product

The Sponsor is responsible for labelling, packaging and shipping the Product (AZD7442 or placebo) to the Site. The Product will be delivered to the Site´s hospital pharmacy.

Sponsor will mandate to a Pharmaceutical Provider (Theradis Pharma), for labelling, packaging and shipping the Product to the Site. Sponsor represents that, at the time of shipment of the Product to the Site the Product: (i) will have been filled, packaged, stored and shipped in accordance with applicable regulatory approvals and all applicable laws and regulations; (ii) will meet all standards and specifications set forth for the Product; and that (iii) batch manufacturing records and the results of all quality assurance tests will have been reviewed and approved by Theradis-authorized manufacturing and quality assurance personnel. Sponsor further represents that it shall obtain and maintain, and use efforts to cause its affiliates and outside contractors to obtain and maintain, all necessary facility licenses, permits or approvals required by applicable laws and regulations in connection with the manufacture, filling, packaging, testing and storage of the Product including, without limitations, permits related to manufacturing facilities.

If Sponsor provides equipment to the Site, a separate Loan Agreement will be executed.

4.2 Stability study, expiry date and recalling of the product batch.

Sponsor shall be responsible for the pharmaceutical quality of the Product until its expiration date. The expiration date of the Product must allow it to be used for the expected duration of the Study.

In the event of a delay in the execution of the Study, Sponsor agrees to replace the expired Product in a timely manner required by the Study.

In the event of a batch recall, and in accordance with cGMP (current Good Manufacturing Practices), Sponsor shall be responsible for recalling that batch of Product from the Study: Sponsor undertakes to immediately send notice by email to the main contact of the Clinical Trial Unit. This one will be responsible to inform the Site. In the event of a recall of batch of defective Product and/or Product assumed to be defective, Sponsor shall use good faith efforts to replace the missing Product(s), within an appropriate time frame and in sufficient quantity to meet the needs of the Study.

4.3 Responsibilities of the Parties towards Sponsor on storing and using the Product properly.

When the Product is provided to the Site the said Party agrees, as the case maybe, to use the Product provided only for the needs specific to conducting the Study for which it is intended under this Agreement. All Parties agree, in particular, not to use the Product outside the Study or for any other dispensation of any kind. The Site will ensure that the Product will be stored adequately in accordance to the storage condition provided by the Sponsor and that no expired Product will be given to any Participant.

4.4 Fate of the unused vials.

At the end of the Study, or at any time if the Study is interrupted or terminated for any reason whatsoever, any unused Products shall be fully accounted for. They shall then be either destroyed on Site or returned at the Sponsor or at the pharmaceutical provider, as instructed by the Sponsor and at the Sponsor's expense.

ARTICLE 5. SAMPLES COLLECTION, TRANSFER, ANALYSIS AND MANAGEMENT

All Parties undertake to use the Samples in compliance with the Participant information sheet and consent form and in-Country laws and regulations.

With regard to the Sample collection and management, including, but not limited to, Sample processing and analyses, Samples transfer and Samples storage activities, the Parties agree to the following:

(a) The Site will be responsible to conduct the Sample collection, labelling, creating and maintaining Samples inventory, and tracking Samples movement in accordance to the Laboratory Manual. The documentation will be made available to the Site upon request.
(b) The Site shall be responsible for all screening assays and all assays for the assessment of safety.
(c) The Site shall be responsible for carrying out the storage of Samples in accordance to the Laboratory Manual.
(d) The Samples will be disposed of/destroyed in accordance with the applicable legislation(s) and the protocol on request of the Sponsor.

The Parties agree:

- The decision on destroying the Samples shall be made by the Sponsor in consultation with the Site. If the Site is no longer able to store the Samples it shall notify the Sponsor accordingly and the Sponsor will arrange for a reasonable resolution. Should additional in-Country approval be required to store the Samples for the afore-mentioned duration

in a Country, the Sponsor shall undertake to obtain such approval and a copy shall be provided to the Site.

- To use the stored Samples solely for purpose of the Study. Any other use for further research has to be, subject to the authorization of the Authorities and Informed Consent of the Participant.
- Not to distribute or release the stored Samples to any third parties not involved in the performance of the Study for any purpose, unless otherwise agreed by the Sponsor and to the extent authorized by the signed Participant consent.
- Not to use the stored Samples in human subjects, in clinical trials, or for diagnostic purposes outside the Study purposes involving human subjects;
- To use the stored Samples in compliance with all laws and regulations applicable.
- Expenses arising from the handling or transport of the Samples supplied will be covered by the Sponsor.

Each Party expressly acknowledges and agrees that the Samples may contain infectious agents and/or agents potentially dangerous. Therefore, no Party can be held liable for any damages, due to any infectious agent and/or agent potentially dangerous, arising from the transport, storage, use or handling of Samples, unless the damage results from a wilful or negligent breach by a Party of its obligation, as defined in the following paragraph, to provide information.

If a Party becomes aware of the presence of infectious agents and/or agents potentially dangerous in Samples, the said Party shall provide the other Party with relevant information in relation with the safety and security of the Samples, as soon as possible.

When Samples are provided by a Party (“provider”) to another Party (“recipient”):

- Except to the extent caused by provider’s negligence or wilful misconduct, the recipient shall hold harmless and defend the provider, including its staff and directors, from and against any claims arising out from the concerned Subject or their dependents, to the extent that such claims are based on negligent non-compliance by the recipient with applicable laws and regulations or provisions of this Agreement regarding modalities of use of the Samples.
- Similarly, the provider providing to the recipient with Samples shall hold harmless and defend the recipient, including its staff and directors, from and against any claims notably arising from the concerned Participant, that would be based on a non-compliance by the provider with applicable laws and regulations or provisions of the Agreement.

Upon early termination of the Study, the Sponsorshall define the terms and conditions of the storage of the Samples collected in the framework of the Study.

ARTICLE 6. ADVERSE EVENT REPORTING AND SAFETY MONITORING PROCEDURE

The Parties agree to comply with the pharmacovigilance standard operating procedure and the Protocol.

ARTICLE 7. DATA PROTECTION

7.1 DATA PROTECTION

The Parties agree to comply with all Data Protection Regulations in processing the personal and sensitive personal data of Participant and to adhere to the principles of medical confidentiality in relation to Participants involved in the Study.

The Sponsor is considered the controller for the processing of the personal data in the framework of the Study.

The Site shall be:data controller when keeping medical records and in the framework of the Study a processor for the Sponsor especially where it will process personal data in accordance with the Protocol for purposes of the Study, while the Personal Data of the Study Subjects will be provided to the Sponsor in a pseudonymized form.

The Parties will both act in accordance with the applicable data protection law. Furthermore, they will cooperate with each other to take the necessary measures in order to comply with the applicable data protection law.

The Site agrees that the Sponsor shall be responsible for collecting consent from the Principal Investigator, all Sub-Investigators and all Personnel (as applicable) to the processing of their personal data by the Sponsor. For the avoidance of doubt, all processing of the personal data of the Principal Investigator, all Sub-Investigators and all Personnel shall at all times be in accordance with the Data Protection Legislation. The Site agrees to provide reasonable assistance to the Sponsor in this regard. In the event that the Principal Investigator, any Sub-Investigator or any member of Personnel refuses to provide such consent, the Parties agree that he/she will not engage in the Study duties.

7.2 Data processing - Processor

7.2.1 General principles

As stipulated in article 7.1 of the current Agreement, Inserm acts in the framework of the Study as the controller in pursuance of Article 4 of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation - GDPR).

Inserm agrees to comply with all legal and regulatory provisions applicable to the processing operations implemented as part of the Study.

The Site acts as a processor as defined in Article 4 of the GDPR. The said Party agrees to comply with all legal and regulatory provisions applicable to the processing operations implemented as part of the Study, especially the GDPR and Czech Act No. 110/2019 Coll., on the processing of personal data, as amended , and to maintain any records as required by the said regulations.

7.2.2 Description of the entrusted processing operations

The purposes of the processing activities, the personal data processed and the categories of Data Subjects are specified in the Protocol provided to the Site by Inserm.

7.2.3 Site's commitment

Without prejudice to the data processing operations under its responsibility as part of its activity, the Site in the position of processor agrees to:

- Process the Data solely for the purposes subject to this agreement and the Protocol.
- Process the Data only on Inserm's documented instructions as defined in the Protocol, and in the SOP set up for the Study and provided by Inserm in the framework of the Study.
- shall immediately inform Inserm if, in its opinion, an instruction infringes the European Data Protection Regulation or any other Union or Member State data protection provisions.

If Site is required to transfer Data to a third country or international organisation by Union or Member State law to which it is subject, it shall inform the Controller of that legal requirement before processing, unless that law prohibits such information on important grounds of public interest.

- Guarantee the confidentiality of all personal data processed as part of this agreement.
- Ensure that persons authorised to process the personal Data in pursuance of this contract (1) have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality, (2) have received the appropriate personal Data protection training.
- Incorporate the principles of data protection by design and by default into its tools, products, applications or services.

7.2.4 Other processors

The Site has no plans to engage other processors to carry out the assigned activities. Site may not engage other processors without prior written authorisation from Inserm.

7.2.5 Duty to provide information to Data Subjects

When collecting Data, the Site must provide the persons whose personal Data will be processed with information on the processing activities carried out in accordance with the information and consent document (original and amended version) supplied by Inserm and approved by the local Competent Authorities.

7.2.6 Exercise of the rights of data subjects

The Site shall assist the Controller in fulfilling its obligation to respond to requests from Data Subjects to exercise their rights: right to access, right to rectification, right to erasure, right to object, right to restriction of processing, right to data portability, and right not to be subject to a decision based solely on automated processing (including profiling).

Therefore,

- When Data Subjects submit a request to exercise their rights directly to the Processor, the Processor shall forward such requests upon receipt by email at Xxxxxxxxxx

- The Sponsor shall provide the Site with answer and
- the Site shall respond, in the name of and on behalf of the Controller and within the period of time specified in the European Data Protection Regulation, to requests from Data Subjects to exercise their rights, with regard to the data covered by the sub-processing arrangement in this agreement.

7.2.7 Notification of personal data breaches

The Site shall notify the Controller of any personal Data breaches without any delay after having become aware of such a breach. This notification must be accompanied by any documents that can help the Controller notify the personal Data breach to the supervisory authority if necessary.

Following consent from Inserm, the Site may communicate, in the name of and on behalf of Inserm (the Controller), to the Data Subject a personal data breach, without undue delay, where that personal data breach is likely to result in a high risk to the rights and freedoms of the natural person.

The communication to the Data Subject shall describe in clear and plain language the nature of the personal data breach and shall at least:

- Describe the nature of the personal data breach including where possible, the categories and approximate number of Data Subjects concerned and the categories and approximate number of personal data records concerned.
- Communicate the name and contact details of the data protection officer or other contact point where more information can be obtained.
- Describe the likely consequences of the personal data breach.
- Describe the measures taken or proposed to be taken by the Controller to address the personal data breach, including, where appropriate, measures to mitigate its possible adverse effects.

7.2.8 Support and assistance from the Site

The Site shall provide Inserm with all necessary assistance in complying with the provisions relating to the processing of personal data, including Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), and relevant national laws.

7.2.9 Security measures

The Site agrees to implement the security measures described in the Protocol.

7.2.10 Fate of personal data

Upon expiration of the agreement and on instructions from Inserm, the Site agrees to:
- Destroy all personal data, or
- Return all personal data to the controller, or
- Return the personal data to any establishment designated by the controller

In addition to returning the personal data, the Institute shall destroy all existing copies in its information systems. Once data have been destroyed, the Institute shall provide written evidence of such destruction.

The Parties agree that this provision must be assessed with regard to the Sponsor's activity and the processing operations for which the Sponsor is responsible in pursuance of Article 4 of the GDPR.

For the avoidance of doubt, the Parties declare that this provision does not apply to the medical documentation of the Site.

7.2.11 Data Protection Officer

The Parties shall send each other the name and contact details of their respective data protection officers. Any communication intended for Inserm's data protection officer must be sent to xxxxxxxxxx.

DPO of the Site: xxxxxxxxxx, tel. xxxxxxxxxx, e-mail: xxxxxxxxxx.

7.2.12 Documentation

The Institute shall make available to Inserm all documentation necessary to demonstrate compliance with its obligations and allow for and contribute to audits, including inspections, conducted by the Controller or another auditor mandated by the Controller in connection with Study.

7.2.13 Record of processing activities

The Processor warrants that it maintains a written record of all categories of processing activities carried out on behalf of the Controller, containing:

- The name and contact details of the Controller on behalf of which the Processor is acting, of any processors and, where applicable, the data protection officer.
- The categories of processing carried out on behalf of the Controller.
- Where applicable, transfers of personal data to a third country or an international organisation, including the identification of that third country or international organisation and, in the case of transfers referred to in the second subparagraph of Article 49(1) of the GDPR, the documentation of suitable safeguards.
- Where possible, a general description of the technical and organisational security measures, including inter alia as appropriate:
    - The pseudonymisation of personal Data.
    - The ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services.
    - The ability to restore the availability and access to personal Data in a timely manner in the event of a physical or technical incident.

- A process for regularly testing, assessing and evaluating the effectiveness of technical and organisational measures for ensuring the security of the processing.

7.2.14 Inserm's commitment

Inserm agrees to:

- Provide the Site with the documents and information specified herein.
- Document any instructions in writing concerning the personal data processing operation by the Site.
- Ensure the Sponsor's compliance with the obligations stipulated in the European Data Protection Regulation before and during the processing period.
- Supervise processing operations, including audits and inspections of the Sponsor**.**

7.2.15 The Parties undertake to cooperate with each other and to assist in resolving any significant problems that may arise in the performance of the Agreement in connection with the protection of personal data. The duty to cooperate also includes effective cooperation in the event of control by the supervisory authority, the handling of requests and possible patient complaints, and the reporting of security incidents. The same applies in the event of a legal dispute concerning the protection of personal data or privacy.

ARTICLE 8. CONFIDENTIALITY

During implementation of the Tasks and for a period of five (5) years after the completion of the Study (or longer if so required by mandatory applicable laws and regulations) any Party (the "Receiving Party") must keep confidential any Confidential Information that is disclosed by or on behalf of another Party (the "Disclosing Party") during the course of the Study and identified as confidential at the time it is disclosed. If information has been identified as confidential only orally, it will be considered to be Confidential Information only if this is confirmed in writing within thirty (30) Days of the oral disclosure.

Unless otherwise agreed between the Parties, they may use Confidential Information only to implement this CTA and the Tasks. No Confidential Information of the Disclosing Party may be used by the Receiving Party for any purpose other than the performance of the Receiving Party's obligations or the exercise of the Receiving Party's rights.

The Party may disclose Confidential Information to their personnel, other individuals under the supervision and control of the Receiving Party, Affiliated Entities, Associated Partners and/or Sub-Contractors involved in the Study only if they: (i) need to know the Confidential Information to implement this Agreement or the Study, and (ii) are bound by obligations of confidentiality at least equivalent to those set forth herein.

Any disclosure of Confidential Information by the Receiving Party to Other Third Parties requires the prior written consent of the Disclosing Party. The Receiving Party must use all reasonable endeavors to ensure that persons and/or entities receiving Confidential Information from it do not disclose such Confidential Information. The Receiving Party shall be responsible to the Disclosing Party for any disclosure by any such personnel, Affiliated Entities, Associated Partners, Sub-Contractors and Other Third Parties, which violates the terms of this CTA, during

and after the end of the Study and/or after the termination of the contractual relationship with the employees or Third Party.

The confidentiality obligations under this Article do not apply if:

- the Disclosing Party agrees in writing that it no longer considers the Confidential Information as protected by the terms of this Article;
- the Confidential Information was already known by the Receiving Party or any of its Affiliated Entities, Associated Partners and/or Sub-Contractors or is given to such parties by an other Party without obligation of confidentiality to the extent such other Party was not bound by any obligation of confidentiality with respect to such Confidential Information;
- the Receiving Party proves that the information was developed independently by the Receiving Party or its Affiliated Entity, Associated Partners and/or Sub-Contractors without the use of Confidential Information;
- at the time of disclosure, the Confidential Information is or after such disclosure becomes generally and publicly available, without breaching any confidentiality obligation by the Receiving Party.

Disclosure of Confidential Information shall be permitted if the Receiving Party is required to do so by or in connection with any laws, regulations or legal processing, or court of competent jurisdiction, provided that such disclosure is subject to all applicable governmental, regulatory or judicial protection available and immediate written notice of such requirement is given to the Disclosing Party with a view to agreeing the timing and the content of such disclosure, if possible.
The same shall apply in case a disclosure of Confidential Information to a patent office or equivalent supervisory required for the purposes of obtaining patent protection, provided, that the Party opting for patent or similar protection must give prior written notice to the Disclosing Party with a view to agreeing the timing and the content of such disclosure.

The Receiving Party shall return to the Disclosing Party all documents or other materials containing any of the Disclosing Party's Confidential Information, which are in its possession, power or control or in the possession, power or control of its personnel, other individuals under the supervision and control of the Receiving Party, Affiliated Entities, Linked Third Parties, Associated Partners and/or Sub-Contractors involved in the Study who have received such Confidential Information from the Receiving Party pursuant to this Article, whenever requested to do so by the Disclosing Party, and where such Confidential Information is not required by the Receiving Party for the use or exercise of (i) Access Rights for completing the Study. The return or destruction of Confidential Information will not affect the Receiving Party's obligation to observe the confidentiality and non-use restrictions in respect of the Disclosing.

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

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

In the event of a Party visiting the establishment of another Party, the visiting Party undertakes that any further Confidential Information which may come to the visiting Party’s knowledge as

a result of any such visit, shall be treated as Confidential Information in accordance with this Article 8.

This Article shall remain in force - after the termination or expiry of this Agreement.

ARTICLE 9. PUBLICITY

Neither Party shall use the name, logo or registered image of the other Party or the employees of such other Party in any publicity, advertising or press release without the prior written approval of an authorised representative of that Party.

The content and timing of any publicity (including without limitation oral presentations and abstracts), advertising or press release shall be agreed by both Parties, such agreement not to be unreasonably withheld.

ARTICLE 10. PUBLICATIONS

The Sponsor is sole responsible to publish alone or with third parties all or part of the Results or Data on all and any media.

ARTICLE 11. INTELLECTUAL PROPERTY

The Results and Data generated by the Parties in Study belong to the Sponsor. Any other Parties has to transfer ownership to the Sponsor.

If such transfer is prohibited by laws and regulations, the Parties involved shall grant the Sponsor, free of charge, with all necessary rights and as the case may be conclude any relevant transfer, licence or other agreement, in order to vest the Sponsor to allow the Sponsor a broad use or exploitation of the Results of Study.

Sponsor shall not own Participants medical records which are, and will remain, the Institution´s property after the completion of the Study.

ARTICLE 12. FINANCIAL AND SUPPLIES ARRANGEMENTS

Appendix 3 to the Agreement defines the flat rate paid by the Sponsor to the Site for each Participant included and followed up in the Study in the Site.

xxxxxxxxxx.

The amounts due under this Agreement will be settled upon presentation of an invoice from the Sponsor 3 months after the end of the inclusion period of the Study. These invoices shall detail the number of Participant included in the Study and the amount due by the Sponsor according to appendix 3 of the Agreement. All invoices will be issued on the basis of mutually agreed documents. These documents will be sent to the addressxxxxxxxxxx

Invoices will be issued with reference to Inserm and addressed to Inserm, xxxxxxxxxx by bank transfer to the following account:

Site bank details:
Bank address: Česká národní banka, pobočka Brno, Rooseveltova 18, 601 10 Brno
Account number: 20001-71138621/0710
IBAN: CZ83 0710 0200 0100 7113 8621
SWIFT: CNBACZPP
IČ: 00159816
DIČ: CZ00159816
Reference number: invoice number

The Parties acknowledge that the expected maximum amount of the total payment under this Agreement is CZK 745 005.

ARTICLE 13. TERM

The date of validity of the Agreement is the date of its execution by the Parties. The Agreement shall remain in effect until completion of the Study (which means the conclusion of all Protocol required activities for all enrolled Participants) and close-out of the Parties or earlier termination in accordance with article 14 of this Agreement.

The effective date of the Agreement is the date of its publication in the Register of Contracts.

The Sponsor consents to the publication of the Agreement by the Site in order to fulfill the obligations imposed by applicable and effective legal regulations, in particular by the Act No. 340/2015 Coll. on Registry of Contracts, as amended, and by the guidelines and decisions of the Ministry of Health of the Czech Republic.

The Site shall ensure not to disclose :
any personal data of natural persons, which are not publicly available in public registers, Confidential Information pursuant to this Agreement, as well as trade secrets, which the Contractual Parties agreed on, pursuant to provisions of § 504 of the Civil Code, notably as follows: protocol and study design, detailed budget, the number of subjects and their remuneration, duration of Study, detailed information about the insurance of the Sponsor. Intellectual property.

For the purpose of the publication of this Agreement within the meaning of this paragraph, the Sponsor shall provide the Site with a redacted version of this Agreement in a machine-readable form to the Site. (ideally in .pdf format).

The Site shall publish the Agreement in the Register of Contracts and shall inform the Sponsor about the publication: (xxxxxxxxxx).

The Site will archive relevant Study Records under adequate conditions that prevent damage or destruction for fifteen (15) years from completion of the Study ("archiving time"). The Sponsor will inform the Site at least 6 months prior the expiry of the archiving time about how these Study Records and related documents will further be handled. If the Sponsor does not inform the Site in time, it is deemed that the Sponsor agrees with document shredding. If the Sponsor requests an extension of the archiving time with the Site, the Site is entitled to charge a proportionate fee to the Sponsor. For the avoidance of any doubt, the Parties state that this does not apply to medical records that are the property of the Site.

ARTICLE 14. TERMINATION

This Agreement may be terminated immediately by notice in writing by a Party:

- If one Party is in material or continuing breach of any of its obligations under this Agreement and fails to remedy the breach (if capable of remedy) for a period of 30 calendar days after written notice by the non-breaching Party; or
- If one Party is declared insolvent or has an administrator or receiver appointed over all or any part of its assets or ceases or threatens to cease to carry on its business.
- If the regulatory permissions and approvals previously granted to perform the Study are withdrawn;
- If funding is withdrawn or terminated for any reason or if it has been agreed that there are insufficient funds available to continue the Study;
- If advised to do so by the study management committee/group, trial oversight committee, study oversight group or other similar arrangements as defined in the Protocol;
- In the event of cessation of supply of Product, medical device, equipment or similar necessary for the Study, or information or resources critical to the Study; or
- If the Principal Investigator becomes unavailable to continue his/her supervision of the Study for any reason and a replacement acceptable to both Parties is not found.

This Agreement can be terminated by the Site by written notice if, as a result of the occurrence of an impediment that occurred independently of its will, the Site will not be able to complete the Study in the long term without adversely affecting its main activity, which is the provision of health care. The notice period shall be 30 days and shall begin to run on the day following the date of delivery of written notice to the other Party.

In the event of termination or expiry of this Agreement, or if the Parties chooses to cease Participant recruitment at its Site/s, the following provisions shall apply:

The Parties shall work together to facilitate an orderly cessation of the Study at the Parties (or cessation of recruitment of Participants at its Site/s where the Parties has chosen to cease recruiting), taking into account the rights, safety, well-being and continuity of treatment (if appropriate) of the Participants and applicable law.
The Parties shall provide to the Sponsor all Study Data and other relevant information and/or data relating to work undertaken by the Parties prior to and including the date of termination and co-operate with all reasonable requests from the Sponsor including any continued monitoring of Participants in accordance with Protocol.

The Parties shall ensure that all reasonable instructions by the Sponsor as regards the return or disposal of all unused supplies, or medical devices or other equipment or items previously provided to the Parties for the purposes of the Study are complied with.

The Parties shall ensure that the instructions of the Sponsor regarding the transfer and/or storage of all information, material or data relating to the Study collected by the Parties in the course of carrying out the Study are complied with.
Unless otherwise agreed in writing with the Sponsor, the costs of storing samples shall be in accordance with APPENDIX 3.

Termination under this article 14 will be without prejudice to any other rights or remedies of either Party under this Agreement or at law, and will not affect any accrued rights or liabilities of either Party at the date of termination.

The Parties will notify the Sponsor if, for any reason, it elects to cease Participant recruitment at its Site/s.

ARTICLE 15. AGREEMENT AND MODIFICATION

The Sponsor has to comply with the provisions of the Grant Agreement and the provisions of the Consortium Agreement currently under review. In the case of any discrepancies with the Grant Agreement and/or with the Consortium Agreement, the current Agreement shall be amended. In the case any of these amendments is denied by the other Party, the current Agreement shall be automatically terminated by the Sponsor. Any amendments to this Agreement shall be valid only if made in writing and signed by authorised signatories of the Parties.

This Agreement including its APPENDICES contains the entire understanding between the Parties and supersedes all other agreements, negotiations, representations and undertakings, whether written or oral of prior date between the Parties relating to the Study.

Services to be performed within the Study by the Parties will be performed in its capacity as an independent contractor and not as an employee or Agent of the Sponsor. Nothing in this Agreement will be construed as implying an employer/employee relationship between the Parties and the Sponsor. Consequently, employees and Agents, including the Investigator and designate(s) of the Parties and its collaborators are not entitled to, and will not receive, any insurance coverage, pension, profit sharing, paid vacation, sick leave, disability, or similar benefit normally provided by the Sponsor to its employees.

ARTICLE 16. FORCE MAJEURE

Force majeure' means any situation or event that:
- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

For the avoidance of doubt, any health crisis situation that consists of a foreseeable but nonetheless exceptional situation and beyond the Parties' control shall be considered as Force majeure.

The following cannot be invoked as force majeure:
- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other Party without delay, stating the nature, likely duration and foreseeable effects. The Parties must immediately

take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible. The Party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

ARTICLE 17. NOTICES

Any notice under this Agreement shall be in writing, signed by the relevant Party to the Agreement and delivered personally, by courier, by recorded delivery post, or by facsimile, or by email, providing evidence of receipt.
Notices to the Sponsor and to the Parties shall be delivered to the addressee and at the address specified in APPENDIX 2 or as may be amended by the Parties during the Study.

Notices:
- by post will be effective upon the earlier of actual receipt;
- by hand will be effective upon delivery; and
- by e-mail will be effective when sent in legible form, but only if, following transmission, the sender does not receive a non-delivery message and providing evidence of receipt.

ARTICLE 18. ASSIGNMENT AND SUBCONTRACTING

No Party shall extinguish or assign all or any part of their rights or obligations under this Agreement without the prior written consent of the other Party, notwithstanding the right of the Sponsor to assign its own Intellectual Property Rights.

Except as agreed between the Parties at the commencement of this Agreement , the Parties shall not subcontract the performance of all or any of its obligations under this Agreement without the prior written consent of the Sponsor, such consent not to be unreasonably withheld or delayed.

The Sponsor(s) may subcontract performance of all or any of its obligations under this Agreement at any time during the term. The Sponsor must notify the Site in writing of this fact.

In the event that either Party subcontracts its responsibilities under this Agreement it shall be responsible for the acts and omissions of its sub-contractors as though they were its own.

ARTICLE 19. DISPUTE RESOLUTION

In the event of any dispute or difference between the Parties arising in connection with this Agreement, the authorised representatives of the Parties will discuss and meet as appropriate to try to resolve the dispute within 30 calendar days of being requested in writing by any Party to do so. If the dispute remains unresolved, it will then be referred to the senior manager from each of the Parties who will use all reasonable endeavours to resolve the dispute within a further 14 calendar days.

If the Parties are unable to resolve a dispute using the procedure outlined in article 19, the Parties may attempt to resolve the dispute by the method defined in article 22 (Governing Law & Jurisdiction).

Each Party shall each bear its own costs in relation to the settlement of any disputes.

Any decision reached in accordance with this article 19 shall be final and binding upon the Parties.

ARTICLE 20. GENERAL

In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Study and the treatment of Participants in connection therewith; in all other respects, the terms of this Agreement shall prevail.

No failure or delay by any Party to exercise any right under this Agreement will operate as a waiver of it, nor will any partial exercise preclude any future exercise of the same.

If any article or part of this Agreement is found by any court, tribunal, administrative body or authority of competent jurisdiction to be illegal, invalid or unenforceable then that provision shall, to the extent required, be severed from this Agreement and shall be effective without, as far as possible, modifying any other article or part of this Agreement and shall not affect any other provisions of this Agreement which shall remain in full force and effect.

Except as expressly stated nothing in this Agreement shall confer or purport to confer on any third party any benefit or any right to enforce any term of this Agreement.

This Agreement may be executed in two counterparts, each of which will be deemed an original, but all of which together shall constitute one and the same instrument.

In accordance with Section 558 (2) of Act No. 89/2012 Coll., The Civil Code, as amended, the Parties expressly exclude the use of business practices in their legal relations in connection with this Agreement.

The Sponsor hereby undertakes not to enter into any other agreement with any employee of the Site at the Site in a connection with this Study.

The integral parts of this Agreement are also the following Appendixes:

- Appendix 1 – Summary of the Protocol
- Appendix 2 – Notification
- Appendix 3 – Study Support Arrangements
- Appendix 4 – Insurance
- Appendix 5 – Principal Investigator Declaration

The Sponsor acknowledges that with regard to Act No. 340/2015 Coll., on the Register of Contracts, as amended, the Site is obliged to publish this Agreement and any amendments thereto in the Register of Contracts. Such disclosure, which constitutes a trade secret of one of the Parties, shall not be subject to such disclosure. The Site is responsible for the publication of this Agreement. If the Site does not publish this Agreement within the statutory period of thirty (30) days, the Agreement may be published by the Sponsor.

ARTICLE 21. SURVIVAL OF ARTICLES

The following articles shall survive the termination or expiry of this Agreement:

- Definitions

- Liabilities and Indemnities
- Confidentiality and Data Protection
- Publicity
- Publication
- Intellectual Property
- Termination
- Survival of Articles
- Governing Law

ARTICLE 22. GOVERNING LAW & JURISDICTION

This Agreement and any non-contractual obligations arising out of or in connection with it are governed by and must be construed in accordance with Czech law. Any disputes arising in connection with this Agreement will be dealt with by a competent and locally competent court of the Czech Republic.

The French National Institute for Health and Medical Research (*Institut National de la Santé et de la Recherche Médicale,* "Inserm"),

Name

(Print)

Title:

Date: 3.12.2021

Signature:

Fakultní Nemocnice U Sv. Anny V Brně

Name Ing. Vlastimil Vajdák

(Print)

Title: Director

Date: 17.12.2021

Signature:

Appendix 1

Xxxxxxxxxx

Appendix 2
Notification

xxxxxxxxxx

APPENDIX3

STUDY SUPPORT ARRANGEMENTS

Xxxxxxxxxx

Appendix 4 – INSURANCE

Xxxxxxxxxx

APPENDIX 5 – PRINCIPAL INVESTIGATOR DECLARATION

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