Contract for the provision of clinical trial activities

Between:
Clinical Trial Center Maastricht B.V.
Seat: Oxfordlaan 70, 6229EV Maastricht, Netherlands
Chamber of commerce: 14063808
Represented by: Carmen Dirksen, CEO
Bank connection: [redacted]
VAT no.: NL808601544B01

(hereinafter referred to as the "**CTCM**")

and

Masaryk University,
Seat: Žerotínovo nám. 617/9, 601 77 Brno
Faculty of Medicine
At: Kamenice 5, 625 00 Brno
TIN: CZ00216224
Represented by: Prof. MUDr. Martin Repko, Ph.D., Dean
bank connection: [redacted]

(hereinafter referred to as the "**Authorised Institution**")

I.
Subject of the contract

1. The CTCM is the designated institution of the sponsor of the clinical trial, Maastricht University Medical Center+, with a seat at P. Debyelaan 25, 6229 HX Maastricht, Netherlands, representing the sponsor in ensuring the sponsor's obligations in the conduct of the clinical trial called "Permanent Left ventricular septAl Pacing versus right ventricular pacing in patients with atrioventricular conduction disorders: a randomised trial: LEAP trial - pilot study (hereinafter referred to as "Study").

2. The subject of this contract is to ensure that a part of the CTCM's duties will be delegated to Authorised institution in implementing the Study on the territory of the Czech Republic. In the Czech Republic, the Study will be conducted at the Fakultní nemocnice Královské Vinohrady with approximately 75 subjects under the direction of the Principal Investigator [redacted] The Authorised Institution shall provide the services within the scope set out in the Annex 1 to this contract.

II.

Obligations of the contracting parties

1. CTCM undertakes to:
   a) provide the necessary cooperation to the Authorized Institution,
   b) provide the Authorised Institution with information on all facts having a significant impact on its activities under this contract without undue delay,

[redacted]

c) to take over the results of the activities of the Authorised Institution,

d) The responsible contact person at CTCM is [redacted], tel. [redacted], e-mail: [redacted]@mumc.nl

2. The Authorised Institution undertakes to carry out the activities specified in Annex 1 to this contract in a proper and timely manner. These activities will be financed following Article III, paragraph 1.

3. The Authorised Institution shall carry out the individual activities within the time limits mutually agreed by the responsible persons of the Parties as set out in this contract.

4. The Authorized Institution is obliged to carry out its activities with professional care, in particular in accordance with the legislation, the instructions of the State Institute for Drug Control, and the requirements of the CTCM.

5. The Authorised Institution undertakes to remedy any defects pointed out by CTCM without delay.

6. If, as a result of a breach of the Authorised Institution's obligations under the contract, CTCM suffers damage, injury and/or incurs costs that would not have been incurred without the breach (in particular, a fine or an obligation to compensate a third party), the Authorised Institution undertakes to reimburse CTCM an amount corresponding to the damage, injury and/or other costs incurred. This contract does not apply to events and situations covered by the insurance policy of CTCM or the Sponsor as a study sponsor.

7. The responsible contact person on the part of the Authorised Institution shall be [redacted] tel.: [redacted] e-mail: [redacted]@med.muni.cz.

8. Changes to the contact persons may be made by written notice sent to the address of the other Party.

III.
Payment terms

1. All activities of the Authorised Institution described in Article II, paragraph 2 and specified in Annex 1 to this contract will be performed by a specialised team within the Faculty of Medicine of MU focused on the support of clinical trials.

2. CTCM is obliged to pay the price for the activities specified in Annex 1 to the Authorised Institution. The budget items listed in Annex 1 are indicative only and may be changed subject to the overall budget.

3. The prices for the services set out in Annex 1 are based on the assumption that the implementation of the Study in the Czech Republic will commence within one centre only and that the Study will be completed within four years of the conclusion of this contract. Suppose more than one site is commenced and/or the duration of the Study is extended. In such case, the Parties undertake to immediately commence negotiations on a new price list for the services provided, reflecting the change in the anticipated costs. If CTCM refuses to do so, the Authorised Institution shall be entitled to terminate this contract with two months' notice.

4. The Authorised Institution shall be entitled to issue an invoice for the preceding calendar quarter in the month following the reference period. The day on which the taxable transaction takes place is always the last day of the calendar quarter.

5. The Authorised Institution shall always be entitled to issue an invoice for the actual hours spent and amount corresponding to the maximum hours and price of the services rendered in the relevant quarter following Annex 1. In case Authorised Institution expects to spend more than the maximum hours as set forth in Annex 1, prior written permission of CTCM shall be required. A

report shall accompany each invoice on the services provided for the period in question. The Authorised Institution shall send the invoices to the following e-mail address of CTCM: [redacted]@mumc.nl The invoice shall be payable within fifteen (15) days from the dispatch date to the e-mail address provided by CTCM.

6. In the event of early termination of this contract in accordance with clause 4 or 10 of this section III or section V, CTCM undertakes to pay for the outstanding activities carried out by the Authorised Institution and the pro rata portion of the activities commenced no later than the date of contract termination.
7. Any extra activities not listed in Annex 1 will be carried out by the Authorised Institution only after the price for such extra work beyond Annex 1 has been mutually agreed. The Authorised Institution shall be entitled to invoice this price for the extra work together with the price for the services according to Article III par. 5 of this contract.
8. In the event of delay in payment of the invoice, the Authorised Institution is entitled to demand a contractual penalty of 0.1% of the amount due for each day of delay until the amount due is paid in full, in addition to the statutory interest on late payment.

IV.
Maintaining confidentiality, data protection

1. All submissions, documentation, information and results related to the Study provided by the CTCM to the Authorised Institution during the term of this contract or to which the Authorised Institution is given access in the performance of its obligations under this contract shall be considered as confidential information of the CTCM unless such information
    a. are or become generally known, i.e., generally available to the public or
    b. are obtained by the Authorised Institution from a third party and not as a result of a breach of this contract, any other agreement or generally applicable law by a Party or a third party.
2. The Parties undertake not to threaten confidentially any trade secrets or confidential information of the other Party or to use it for any purpose other than as set out in this contract unless the Party is obliged to disclose it through no fault of its own by law or by a binding, final order of a court or public authority. The obligation under this paragraph shall continue to be binding on the Parties after the termination of this contract, without time limitation, unless the information ceases to be confidential or the term of protection of the subject matter of the rights expires.
3. The provisions of this Article are without prejudice to the obligation of the Parties to publish this contract and/or any part thereof if required by law (e.g. Act No. 106/1999 Coll. of the Czech Republic, on Free Access to Information, as amended, Act No. 340/2015 Coll. of the Czech Republic, on the Register of Contracts, as amended).
4. To the extent the Authorised Institution is given access in the performance of its obligations to personal data of Study subjects, the Authorised Institution shall act in accordance with the 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 (General Data Protection Regulation) and local implementing law, as well as the informed consent form.

V.

Early termination of the contract

1. The Parties shall be entitled to terminate this contract by written notice effective upon delivery to the other Party in the following cases:

   a) if either Party fails to comply with or perform any of the provisions of this contract and fails to remedy the defective condition even within 15 calendar days after receipt of a notice to remedy,

   b) in the event of a material breach of a contractual obligation, in particular:

   - delay of the Authorised Institution in fulfilling the subject of this contract;

   - breach of the obligation of confidentiality or data protection under Article IV of this contract.

VI.
Final Provisions

1. Legal relations not expressly regulated by this contract shall be governed by the laws of the Czech Republic.
2. This contract shall enter into force on the date of its signing by both Parties and shall become effective on the date of its publication in the Register of Contracts in accordance with Act No.340/2015 Coll. of the Czech Republic, on Special Conditions for the Effectiveness of Certain Contracts and on the Register of Contracts, as amended. The Authorised Institution is obliged to ensure that the contract is published in the Register of Contracts without undue delay after its conclusion and notify the CTCM of this fact. The parties shall, at the latest at the time of conclusion of the contract, identify those parts of the contract which they consider to be their trade secrets and which are, therefore, not subject to the obligation to publish in the register of contracts.
3. This contract is concluded for a definite term until the earlier of a) the completion of the Study and last payment made by CTCM, or b) the fourth (4th) anniversary of this contract.
4. This contract is executed electronically by means of the attachment of electronic signatures in accordance with Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC.
5. Amendments and additions to this contract may only be made by written amendment to the contract.
6. The annexes to this contract form an integral part of this contract
   a. Annex 1 - Division of activities in the implementation of the Study and Price Budget for the Activities of an Authorised Institution

In Brno on date:

In Maastricht on date: 27 februari 2024

[redacted]

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prof. MUDr. Martin Repko, Ph.D.
Dean of LF MU

Carmen Dirksen
CEO Clinical Trial Center Maastricht B.V.

Annex 1 - Division of activities in the implementation of the Study and Price Budget for the Activities of an Authorised Institution

1 site (Prague - FNKV)
4 years
1 SIV + 2MV + 4 RMV + 1 COV

LEAP

[redacted] EUR commercial price

1 site (Prague - FNKV)
4 years
1 SIV + 2MV + 4 RMV + 1 COV

	Nº HOURS	UNITS	Cost/Hour	TOTAL COST
MONITORING				
CRA training (*no. of monitors)	[redacted]			
Preparation of ISF, PSF (per centre)				
Maintenance of investigator's trial master file during the study duration (*no. centre, *no. years)				
Investigators meeting				
Preparation, conductance and report of initiation visit including pharmacy visit (1 centre)				
Remote Monitoring « on-line » (Web-based) (per 1 centre)				
Communication with site & communication with monitor, sponsor, ISF, TMF (*no. centre, *no. months)				
Preparation, conductance and report of regular monitoring visit (*no.visits, *no. centres)				
Preparation, conductance and report of close-out monitoring visit (including pharmacy visit) - (*no. centres)				
Report review (* no. of reports)				
Travel costs				
Creation of final report for CA				
Queries resolution and database lock (per 1 centre, one year)				
				15.724 EUR