

## Contract on cooperation in clinical trial activities

Between:

**Copenhagen University Hospital – North Zealand**

Seat: Dyrehavevej 29, 3400 Hillerød, Denmark

VAT no.: 30167686

Represented by: Professor Morten H. Bestle, as authorised by CUH

(hereinafter referred to as the "CUH")

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:

(hereinafter referred to as the "Authorised Institution")

### I.

#### Subject of the contract

1. The CUH has, through Professor, MD, PhD Morten Bestle, legal responsibility as the sponsor of the clinical trial called "Goal directed fluid removal with furosemide in intensive care patients with fluid overload – A randomised, blinded, placebo-controlled trial (GODIF)" EU number: 2024-512186-14-00 (hereinafter referred to as "Study").
2. The subject of this contract is to ensure that a part of the CUH'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 three centers: Fakultní nemocnice Plzeň, Fakultní nemocnice Ostrava, IKEM Praha. 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. CUH 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,
  - c) to take over the results of the activities of the Authorised Institution,
  - d) when publishing all results and reports from the Study, includes in all materials the text "Supported by the national budget through MEYS, LRI CZECRIN (LM2023049)."The Authorised Institution is entitled to unilaterally modify the wording of the above

dedication by sending the new wording via e-mail to the CUH contact person.

- e) The responsible contact person at CUH is [REDACTED], e-mail: [REDACTED]
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 CUH.
  5. The Authorised Institution undertakes to remedy any defects pointed out by CUH without delay.
  6. If, as a result of a breach of the Authorised Institution's obligations under the contract, CUH 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 CUH 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 CUH or the Sponsor as a study sponsor.
  7. CUH, as a sponsor, is fully responsible for the implementation of the study within each centre. In the event that the Authorised Institution becomes aware of a violation of the study protocol, good clinical practice or other binding legal or sub-legal regulations by the persons conducting the study within the individual centres, the Authorised Institution is obliged to inform CUH of this fact, and the Authorised Institution shall not be liable for any damages caused by such fact. CUH is then fully responsible for arranging remedies and ensuring the proper continuation of the study without undue delay. In the event of failure to remedy the situation within a reasonable period of time, the mandated institution shall be entitled to withdraw from this contract in accordance with Article V. par. 1. Letter a) of this contract.
  8. The responsible contact person on the part of the Authorised Institution shall be [REDACTED]
  9. 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 academic clinical trials and funded by the project CZECRIN - Czech National Node of the European Clinical Research Infrastructure Network (LM2023049).
2. CUH is obliged to pay the price (costs including overheads) 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. Travel costs will be invoiced on the basis of actual costs incurred following the internal guidelines of the Authorised Institution and the relevant legal standards, including overheads, up to the amounts indicated in the travel costs table.
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 three centres only and that the Study will be completed within 42 months of the conclusion of this contract. Suppose



more than three sites are 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 CUH 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 on 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 work done 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 CUH 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 CUH: [REDACTED] The invoice shall be payable within forty (40) days from the dispatch date to the e-mail address provided by CUH.
6. In the event of early termination of this contract, CUH 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.
9. The CUH must inform the Authorised Institution of all third parties involved in the Study in whatever capacity and form, both current and future, and how the Study will be funded. Suppose the participation of a third party in a Study or a change in the method of funding the Study could jeopardise the designation of the Study as an academic study. In that case, this will be considered a material change in circumstances. In such a case, the Parties undertake to enter into negotiations to modify the terms of the cooperation under this contract. Should no agreement between the Parties be reached within 60 calendar days from the date of the event that is considered a material change of circumstances under this paragraph, the Authorised Institution shall be entitled to terminate this contract without notice.
10. CUH agrees not to provide any data obtained from the clinical study to commercial entities for the duration of this agreement and for three years from the date of termination of this agreement. The CUH acknowledges that a breach of this provision could jeopardise the implementation of the LF MU CZECRIN - Czech National Node of the European Network of Clinical Research Infrastructures (LM2023049) project and shall be liable for the full amount of the damages associated therewith, and acknowledges that the resulting damages may exceed the total value of this contract. The parties expressly state that the publication of the results of the clinical study to a professional audience (article in a professional journal, presentation of the results at a professional conference) is not a breach of CUH's obligation under this provision.

#### **IV.**

##### **Maintaining confidentiality, data protection**

1. All submissions, documentation, information and results related to the Study provided by the CUH



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 CUH 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.
2. The Authorised Institution is also entitled to terminate this contract if the financing of the LF MU CZECRIN project specified in Article III of this contract is terminated. Termination under this paragraph shall take effect upon the expiry of a notice period of one calendar month commencing on the first day of the calendar month following the delivery of the notice to the CUH.

## **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 CUH 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 completion of the Study and last payment made by CUH.
4. This contract is executed in duplicate with the force of an original by the affixed signatures of authorized representatives of the Parties, each Party shall receive one such copy.
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:

28. 08. 2025



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

In Hillerød on date:

5/8-2025



Professor, MD, PhD Morten Bestle  
Sponsor authorised by CUH





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

## GODIF

3 sites (FN Plzeň, FN Ostrava, IKEM)

1 SIV + 2 MV + 1COV

End of trial 03/2028

	N° HOURS	UNITS	Cost/Hour	TOTAL COST
CRA training (*no. of monitors)				
Preparation of ISF, PSF (per centre)				
Maintenance of investigator's site 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 (every year) and database lock (* centre, * year)				
<b>Total</b>				<b>14 398 EUR</b>