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Č. činnosti
Č. FÚ 0001
Datum 5. 12. 2019 Podpis [redacted]

Monitoring cost agreement for the CLASSIC trial

The Conservative vs. Liberal Approach to fluid therapy of Septic Shock Intensive Care (CLASSIC) Trial

A randomised, blinded, placebo-controlled trial

THIS AGREEMENT IS MADE BY AND BETWEEN (hereinafter referred to as the "Agreement"):

Anders Perner
Department ICU 4131
Copenhagen University Hospital Rigshospitalet
Blegdamsvej 9
DK-2100 Copenhagen, Denmark
E-mail: [redacted]@regionh.dk
Represented by:

Hereinafter referred to as "Sponsor"

AND

Masaryk University, whose registered office at Zerotinovo nam. 617/9, Brno 601 77, Czech Republic, ID number 00216224, VAT num.: CZ00216224

Represented by: doc. MUDr. Martin Repko, Ph.D., the dean of **Faculty of Medicine,** contact address: Kamenice 5, Brno-Bohunice, 625 00, Czech Republic

Hereinafter referred to as "MU" or "**monitor**", who offer monitoring services for the CLASSIC trial in the Czech Republic.

This agreement concerns only cost covering for monitoring the CLASSIC trial and has been concluded based on the trial description in protocol version 2.2 and based on the monitoring plan, which primary GCP coordinator and Sponsor agrees on. The monitoring plan is expected to be complied.

Study title:	The Conservative vs. Liberal Approach to fluid therapy of Septic Shock in Intensive Care (CLASSIC) Trial.
Protocol version	2.2 and date 13/11/2018.
EudraCT-number	2018-000404-42
National Investigator (NI):	[redacted] Medical Intensive Care Unit 1.Interni klinika

Fakultni nemocnice
Alej Svobody 80
Plzen 30460
Czech Republic
E-mail: [redacted]@gmail.com

Sponsor:

Anders Perner
Department ICU 4131
Copenhagen University Hospital Rigshospitalet
Blegdamsvej 9
DK-2100 Copenhagen, Denmark
E-mail: [redacted]@regionh.dk

Study-Centre	Fakultni nemocnice u sv. Anny, Brno, Czech Rep.
Study Duration	Approximately [2] years, Recruitment approx. [1,5] years
Monitor Duration	Approximately [2] years as final monitoring visit is 90 days after last patient is randomised.
Number of Patients	25 estimated

Confidentiality

Monitor will work under strictly confidential conditions and will not use the sources for its own purpose or other than as described in the monitoring plan. For purposes (stated below) confidential information shall not include, and the obligations of confidentiality and use shall not apply to, information that:

- is or becomes publicly available through no fault of the monitor,
- is disclosed to monitor by a third party, provided such third party possesses the legal right to disclose such information.
- is demonstrated as independently developed or acquired by monitor
- is already known to monitor as shown by its prior written records,
- is required to be disclosed by monitor to administrative and regulatory bodies for the performance of the Services
- is required by law to be disclosed, in which case monitor will inform as soon as possible at the latest within 24 hours since monitor has been informed of any possible steps that might lead to such an event.

Notwithstanding the foregoing, monitor may disclose the confidential information to other consultants who have a legitimate need to know the confidential information for the purposes set forth in this Agreement.

In the performance of the services pursuant to this Agreement, monitor may seek the collaboration of third parties. In any case monitor will be solely responsible of the performance of the services and has to get written consent beforehand from NI/Sponsor.

Sponsor acknowledges that MU is an obligated subject under the Czech act no. 340/2015 Coll. of the Czech Republic, on special conditions for the effectiveness of some contracts, the disclosure of these contracts and the Registry of contracts (Act on the Registry of contracts). Provisions of the Act on the Registry of contracts obligates public institutions (such as Masaryk university) to transparently publish a copy of this agreement (including metadata) in a central repository of contracts (Registry of contracts) before the agreement enters into force.

Sponsor and MU declare that they agree that this Agreement and all its amendments will be published by MU in the Register of contracts under the conditions of the Act on the Registry of contracts.
Sponsor and MU declare that the confidential parts of this Agreement and its amendments, third party trade secrets and parts protected by intellectual property, such as the Protocol, will not be published in the Register of contracts.

The parties have agreed, that the annexes (appendices) of this Agreement will not be published, because they contain intellectual property, know-how and trade secrets of the Sponsor and/or MU.

Term and Termination

This Agreement is considered concluded as from the date of signature of the last Party to sign the agreement. The effective date is the date when a copy of this agreement has been published in a Registry of contracts and shall remain in effect until the end of the Services quoted under Monitor Duration or terminated by one of the Parties.

Either Party may terminate the monitor plan in whole or in part, with or without cause, upon 30 (thirty) days advance written notice to the other Party. Upon termination, where practical, **monitor,** will cease all work in progress without compromising the integrity or quality of the work in progress and bringing it to a logical conclusion, as agreed upon by the Parties. In this event, Sponsor will pay to **monitor** all sums owing for the Service carried out up until the termination.

Either Party shall have the right to withdraw from this contract, with an immediate effect, by serving written notice via registered mail with return receipt, if any of the following events occurs upon:

- Insolvency;
- Declaration of bankruptcy.

The withdrawal will take effect from the date on which the notification is delivered.

Data

The Parties agree to comply with Applicable Law, hereunder the EU General Data Protection Regulation, throughout the term of the Agreement. It is the responsibility of each Party to effect and maintain all inventories and registrations for the processing of personal data as required under Applicable Law. The Parties shall cooperate and assist each other with respect to any data protection impact assessments and/or prior consultations with government authorities that may be required in respect to processing that is carried out under the Agreement.

Law and venue

In the event of any dispute arising between the Parties in relation to the terms of this Agreement, the Parties shall use their best endeavours to resolve the matter on an amicable basis. This Agreement shall be governed by and shall be construed in accordance with the laws of Denmark without regard to any conflicts of law's provisions. The Parties consent to the competent courts of Denmark for the resolution of all disputes or controversies between the Parties hereto that the Parties are unable to settle amicably.

Compensation

The total price for all Tasks described below is 2800,- EUR excluding VAT. Payments will be made pro-rata for work completed, on a quarterly basis. MU shall submit an invoice and report summarizing the work completed to Sponsor at the e-mail address below.

The services will be paid for by Centre of Research in Intensive Care (CRIC) and the invoice is to be sent to [redacted]@cric.nu. You may need the following information: VAT DK29765790. Payment 30 days from the date indicated in the invoice.

Monitoring	**Hours per study-Centre (in all)**		**An hours (EUR)**	**EUR**
Monitoring set-up (incl. reading of Study-Protocol, CRF, Monitoring Plan), first contact with responsible study-coordinator (NI)/Sponsor and site.	[redacted]			
Site Initiation Visit (first contact with responsible study coordinator (NI)/Sponsor). Incl. preparing and follow-up reporting.				
Monitoring Visits Two visits (levels) incl. pre-processing and reporting ***Level I** Systematic data verification of all data in the case report form. Applies to the first 3 trial participants and hereafter until a total of 10% of participants for each trial site has been monitored. ***Level II** Selected data on all trial participants, who has not been selected for "Level I" Levels of monitoring visits are explained in detail in CLASSIC Data Verification Plan.				
Close-Out Visit 1 Study-Centre, 1 visit á 16 hours (incl. preparing and follow-up reporting)				
Total	80		35	2800

*Further details of levels are to be found in the CLASSIC Data Verification Plan.

Sponsor and MU agree that in case that there is a need to conduct more monitoring visits than already scheduled above, Sponsor undertakes to pay MU the Price of an additional monitoring visit in the amount of 600,- EUR (without VAT) per conducted monitoring visit. MU will not conduct any additional monitoring visit without a prior written consent of Sponsor.

Signatures

This Agreement is executed in two counterparts, depending on the number of the parties, each of which shall be considered an original hereof, but which together shall constitute one agreement.

Monitoring services

Date: - 2 -12- 2019

Signature [redacted]

Name Martin Repko

Titel the dean of Faculty of Medicine

Sponsor

Date: [redacted]

Signature: [redacted]

Jan Bonde

Head of department

Date: [redacted] 6/11/19

Signature: [redacted]

Anders Perner

Sponsor, Professor, MD, PhD