

**Monitor 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

**Name of institution providing the services:**

Address: []

Contact person: []

Phone: []

[Name] hereby offer monitoring services for the CLASSIC trial in XXX.

*This agreement concerns only cost covering for monitoring the CLASSIC trial and has been concluded based on the trial description in protocol version 2.1 and based on the monitoring plan, which primary GCP coordinator and Sponsor agrees on. The monitoring plan is expected to be complied.*

*The Clinical Trial Agreement between National Investigator and Sponsor contains conditions as confidentiality, term & termination, which are the same for the monitor.*

**Study title:** The Conservative vs. Liberal Approach to fluid therapy of Septic Shock in Intensive Care (CLASSIC) Trial.

**Protocol version** 2.1 and date 3/5/2018.

**EudraCT-number** 2018-000404-42

**National Investigator:** Name

Address

E-mail

**Sponsor:** Anders Perner

Department ICU 4131

Copenhagen University Hospital Rigshospitalet

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DK-2100 Copenhagen, Denmark

E-mail: [anders.perner@regionh.dk](mailto:anders.perner@regionh.dk)

**Study-Centre** Sites in total in (Country)

**Study Duration for Sweden** Approximately [] years, Recruitment approx. [] years v v

**Number of Patients** [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.

**Term and Termination**

This contract will commence on the Effective Date 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.

The services will be paid for by CRIC and the invoice is to be send to [contact@cric.nu](mailto:contact@cric.nu). You may need the following information: VAT DK30167686

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| --- | --- | --- | --- | --- |
| **Monitoring** | **Hours per study-Centre** | **Hours for all study-centers** | **An hours (EUR)** | **EUR** |
| **Monitoring set-up**  (incl. reading of Study-Protocol, CRF, Monitoring Plan), first contact with responsible study-coordinator/Sponsor and site. |  | 20 |  |  |
| **Site Initiation Visit (**first contact with responsible study-coordinator/Sponsor and site). |  | 10 |  |  |
| **Site Initiation Visit** (Other Sites)  Incl. preparing and follow-up reporting. | 6 |  |  |  |
| **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. | 16  30 |  |  |  |
| **Close-Out Visit**  1 Study-Centre, 1 visit á 16 hours (incl. preparing and follow-up reporting) | 2 |  |  |  |
| **Total** | 54 |  |  |  |

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

**Signatures**

Monitoring services Sponsor

Date: [] Date: []

Signature: Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[type title and name] Professor, MD, PhD Anders Perner