

**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

Blegdamsvej 9

DK-2100 Copenhagen, Denmark

E-mail: 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]

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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. | 1630 |  |  |  |
| **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