

**Monitoring Contract 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 Sweden.

This agreement has been concluded based on the trial description in protocol version 2.1

**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

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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

**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) Incl. preparing and follow-up reporting.  |  | 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. | 1616 |  |  |  |
| **Close-Out Visit**1 Study-Centre, 1 visit á 16 hours (incl. preparing and follow-up reporting) | 16 |  |  |  |
| **Total** |  |  |  |  |

**\***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

CRIC Project Manager

Date:

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

RN, MSc (Health Science), Maj-Brit Nørregaard Kjær