Report of serious adverse reactions/events

**PART 1:** Serious adverse reactions/events (from investigator to Sponsor)

**PART 2:** Serious adverse reactions/events (Sponsors assessment)

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

EudraCT number: 2018-000404-42

Protocol number: RH-ITA-007

**PART 1 (To be filled in by Investigator)**

**Report date** (dd-mm-yyyy)**:**

**Report type**

 Initial [ ]  Follow up [ ]

**Participant information**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Patient initials | Country | Date of birth (dd-mm-yyyy)  | SexM [ ]  F [ ]  | Height:Weight: |
| Trial participant ID | Name of site |

**Serious adverse reactions/events**

A serious adverse reaction/event is life-threatening, requires hospitalisation or prolongation of existing hospitalisation or results in persistent or significant disability or incapacity.

If a serious adverse reaction/event occurs please remember

1) the trial intervention may be discontinued at the choice of the investigator

2) data entry should be continued

|  |  |
| --- | --- |
| Serious adverse reaction/event onset date (dd-mm-yyyy) | Serious adverse reaction/event end date (dd-mm-yyyy) |
| Patient discontinued from study intervention due to serious adverse reaction/event Yes [ ]  → date (dd-mm-yyyy): time (hh:mm). No [ ]   |

**Evaluation of the serious adverse reaction/event**

|  |  |  |
| --- | --- | --- |
| **Outcome** |  |  |
| Ongoing reaction |[ ]   |
| Resolved |[ ]   |
| Fatal |[ ]   |
| Unknown |[ ]   |

**Death**

|  |  |
| --- | --- |
| Date of death (dd-mm-yyyy) | Cause of death |

Relationship of the event and intravenous fluid

|  |  |
| --- | --- |
|  Unrelated to the intravenous fluid [ ]  (No, unlikely) |  Related to the intravenous fluid [ ]   (Possible, probable, definite) |

Causability information

|  |
| --- |
| Did the reaction abate after discontinuing the trial intervention?  Yes [ ]  No [ ]  NA [ ]   |

Event Description

Concomitant medication(s) relevant to the event (exclude those used to treat the event)

|  |
| --- |
| Concomitant drug(s) and dates (dd-mm-yyyy) of administration. |

**Reporter information Investigator information**

|  |  |
| --- | --- |
| Name: | Name: |
| Address: | Address: |
| Phone:+ | Phone:+ |
| Profession: | Profession: |
| Signature & date (dd-mm-yyyy) | Signature & date (dd-mm-yyyy) |

Fill in this form and e-mail it to the coordinating centre

**E-mail:** classic@cric.nu

Sponsors signature for receiving this report:

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

**PART 2: (To be filled in by sponsor)**

Causality assessment by Sponsor:

**1. Result of causality evaluation**

[ ]  Not related to study drug (Unlikely/doubtful) → (If not judged related, please comment in box 4)

[ ]  Related to study intervention (Possible/Probable/Definite) → (Go to box 2 below)

**Expectedness** **assessment by Sponsor (only relevant if the serious adverse reaction/event is related to the study drug):**

**2. Result of the expectedness evaluation**

[ ]  Expected (due to relevant reference document)

[ ]  Unexpected→ (Go to box 3 below)

**Summary:**

**3. Category of event**

[ ]  SUSAR (SAR is both related and unexpected)

[ ]  SAR (SAR is related but not unexpected)

**Notify relevant authorities according to protocol**

Sponsors comments:

**4.**

Sponsors signature:

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