Reporting of serious adverse events

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

PART 2: Serious adverse events (Sponsor's assessment)

Protocol title: Higher vs. Lower Doses of Dexamethasone in Patients with COVID-19 and Severe Hypoxia: the COVID STEROID 2 trial

EudraCT number: 2020-003363-25

Protocol number:

Ethics committee number:

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)	Sex M ☐ F ☐	Height: Weight:
Trial participant ID	Name of site			

<u>Serious adverse events</u>

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

If a serious adverse 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 event onset date (dd-mm-yyyy)	Serious adverse event end date (dd-mm-yyyy)
Patient discontinued from study intervention due to serious adverse event Yes ☐ → date (dd-mm-yyyy): time (hh:mm). No ☐	

Evaluation of the serious adverse event

Outcome	
Ongoing reaction	☐
Resolved	☐
Fatal	☐
Unknown	☐

Death

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

Relationship of the event and trial medication

Unrelated to trial medication☐	Related to trial medication ☐
(No, unlikely)	(Possible, probable, definite)

Causality information

Did the reaction abate after discontinuing the trial intervention?
Yes ☐ No ☐ Not applicable ☐

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: covid-steroid@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 (SUSAR is both related and unexpected)
☐ SAE (SAE is not trial medication) this should be reported to sponsor or coordinating investigator within 24 hours

Notify relevant authorities according to protocol

Sponsors comments

4.

Sponsors signature:

Date: _____ Signature: _____