

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-y	/yy):					
Report type						
Initial 🗆		Follow up				
Participant information	1					
Patient initials	Country	Date of birth	Sex		Height:	
		(dd-mm-yyyy)	м□	F 🗆		
Trial participant ID	Name of site				Weight:	
Serious adverse events						
A serious adverse even	t is life-threatening	g, requires hospitalis	ation or	prolongation	of existing hospitalis	sation or
results in persistent or	significant disabilit	ty 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						

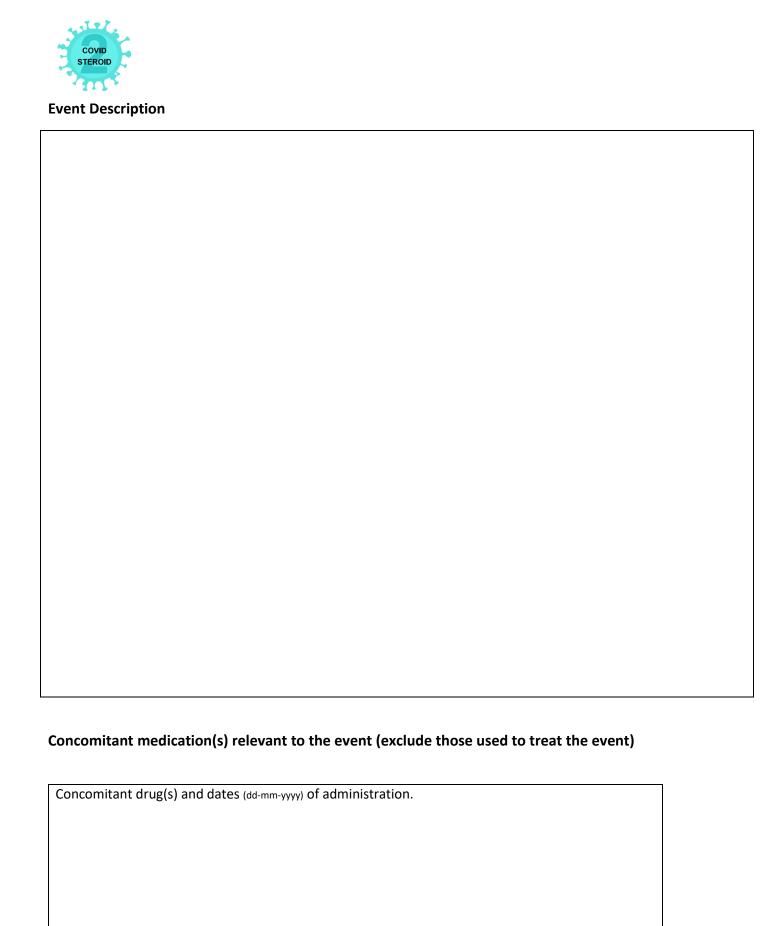


Serious adverse event onset date (dd-mm-	Serious adverse event end date (dd-mm-yyyy)		
уууу)			
Patient discontinued from study intervention due to serious adverse event			
_	_		
Yes $\square \rightarrow$ date (dd-mm-yyyy): time	(hh:mm). No □		
Yes $\square \rightarrow date (dd-mm-yyyy)$: time	(hh:mm). No □		



Evaluation of the serious adverse event

Outcome		
Ongoing reaction		
Resolved	1	
Fatal	1	
Unknown	1	
Death		
Date of death (dd-mm	n-yyyy)	Cause of death
Relationship of the e	event and trial medication	
Unrelated to trial med	dication□	Related to trial medication \square
(No, unlikely)		(Possible, probable, definite)
Causality informatio	n	
Did the reaction abate	e after discontinuing the trial	intervention?
Yes □ No □	Not applicable □	





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 coordina	iting 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
\square Not related to study drug (Unlikely/doubtful) \rightarrow (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: