



Randomised Evaluation of COVID-19 Therapy

**THIS FORM IS FOR REFERENCE ONLY.
ALL DATA ENTRY IS COMPLETED ONLINE.**

1. Report type *	SAE number *	Form number (for this SAE) *
<small>If this is the first time the SAE has been reported, please select "Initial report". If you are submitting new, updated or corrected information for a previously reported SAE, please select "Follow-up information".</small> <input type="radio"/> Initial report <input type="radio"/> Follow-up information	<small>If this CRF relates to the patient's first SAE, enter 1. If the patient has had more than one SAE, please record the SAE number that this applies to</small>	<small>If this is the initial report, enter 1. If this is a follow-up form, please record the number of CRFs you have attempted to complete for this SAE, including this one</small>
2. Site		
Site name	Site name (if not in list)	
3. Participant details		
Study number		
Participant's initials		
Date of birth *		
yyyy-mm-dd		
Sex <input type="radio"/> Male <input type="radio"/> Female		

4. Adverse Event description <i>Please record diagnosis if known, an account of the event including signs and symptoms if diagnosis not known, any interventions given to manage the event including dates for these and if event fatal, cause of death if known</i>		
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5. Start date of SAE yyyy-mm-dd <hr/>	Start time of SAE <i>(hh:mm [24 hr])</i> <hr/>	
6. Stop date of SAE yyyy-mm-dd <hr/>	Stop time of SAE <i>(hh:mm [24 hr])</i> <hr/>	or Ongoing? <input type="radio"/> Yes
7. Date site became aware of SAE yyyy-mm-dd <hr/>	Time site became aware of SAE <i>(hh:mm [24 hr])</i> <hr/>	
8. Please record severity of event <input type="radio"/> Mild <input type="radio"/> Moderate <input type="radio"/> Severe		
9. Reason this event is classed as Serious <i>If there is more than one reason which applies then choose the more/most significant one and document other reason(s) in the AE description</i> <input type="radio"/> Fatal <input type="radio"/> Life threatening <input type="radio"/> Requiring/prolonging hospitalisation <input type="radio"/> Congenital anomaly/birth defect <input type="radio"/> Significant disability/incapacity <input type="radio"/> Other important medical event		
10. Relevant medical history <i>Provide a full description of any medical history which could be relevant to this SAE and which may need to be considered by the individual reviewing the event (including co-existing medical conditions, allergies or similar experiences)</i>		
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11. Laboratory results relevant to the SAE <i>Please give details of relevant results, dates and reference ranges in the space below or send a printout with these details highlighted and patient identifiable information obscured</i>		
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12. Specify the study drug details below

Study drug name	Dose	Frequency	Route	Date started yyyy-mm-dd	If discontinued, date stopped yyyy-mm-dd
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Did the event resolve after stopping study drug?

☐ No ☐ Yes ☐ N/A

Did the event reappear after reintroduction?

☐ No ☐ Yes ☐ N/A

Action(s) taken with study drug

- ☐ None
☐ Discontinued temporarily
☐ Dose reduced
☐ Discontinued
☐ Dose temporarily reduced

13. Concomitant medication

Concomitant medication?

☐ None

» Describe all non-study medication taken at the time of onset of the event and medication given to treat the SAE including prescription, non-prescription and over-the-counter medication

Medication	Indication	Given to treat SAE? <input type="radio"/> Yes	Dose	Frequency	Route
Date started yyyy-mm-dd			If discontinued, date stopped yyyy-mm-dd		

14. Outcome of event <input type="radio"/> Resolved <input type="radio"/> Resolving Not Resolved <input type="radio"/> Resolved with sequelae <input type="radio"/> Unknown Fatal
Date of death <div>yyyy-mm-dd</div>
Was a post-mortem performed/is one planned? <input type="radio"/> Yes <input type="radio"/> No
Date of post-mortem <div>yyyy-mm-dd</div>
Further information
15. Is there any further information to come? * <i>Follow-up information should be submitted on any unresolved event until resolution</i> <input type="radio"/> Yes <input type="radio"/> No
When further information is available, please use another SAE Report Form and only report any new or changed information <div></div>
16. Reporter's Signature <div></div>
Date of completion <div></div>
Printed Name <div></div>
Position <div></div>
Telephone Number <div></div>
Further contact details <div></div>

17. Causality of the SAE

The Investigator's decision on relationship to the IMP

☐ Not related ☐ Possibly ☐ Probably ☐ Definitely

Investigator's signature

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Date

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Printed name

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Position

.....

Telephone Number

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Further contact details

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Notes

Please add any additional comments here

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