

Please complete all sections with details of any SAE occurring from randomisation until 48 hours after final extubation. For guidance on which events to report please see study protocol and SOP 008 – Safety monitoring. **Please send this form to the ICNARC CTU within 24 hours of notification of the event.**

Study details			
Study title:	A Randomised Multiple Centre Trial of Conservative versus Liberal Oxygenation Targets in Critically Ill Children		REC reference: 19/EE/0362

Patient details			
Patient trial number:	<input type="text"/>	Age:	<input type="text"/> days / weeks / months / years
Patient hospital number:	<input type="text"/>	Study arm:	<input type="checkbox"/> Target SpO ₂ : 88-92%
Site name:	<input type="text"/>		<input type="checkbox"/> Target SpO ₂ : >94%
Type of report:	<input type="checkbox"/> First <input type="checkbox"/> Update <input type="checkbox"/> Final	Treating Clinician:	<input type="text"/>

	Start date d d m m y y	Start time 24-hour clock	End date d d m m y y	End time 24-hour clock
Intervention	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Event summary description	<i>(Give a concise medical description of the all relevant symptoms, and complete page overleaf for all events that meet the definition of serious)</i>	Continued on a separate sheet: <input type="checkbox"/> Y <input type="checkbox"/> N
No. of events included in this report: <input type="text"/>		

Any relevant medical history / concurrent conditions? <input type="checkbox"/> Y <input type="checkbox"/> N	<i>(If yes, please specify below)</i>
Was event expected in view of patient's medical history? <input type="checkbox"/> Y <input type="checkbox"/> N	

Patient trial number:

Serious Adverse Event (SAE)

COMPLETE A SEPARATE PAGE FOR EACH EVENT THAT MEET THE DEFINITION OF SERIOUS (photocopy this page as necessary for each event)

Name of event	Severity	Start date	Start time	Date resolved
	1 = Mild 2 = Moderate 3 = Severe 4 = Life threatening 5 = Fatal	d d m m y y	24-hour clock	d d m m y y
	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Why was the event serious (tick all that apply)				Outcome			
<input type="checkbox"/>	Resulted in death	<input type="checkbox"/>	Life-threatening	<input type="checkbox"/>	Resolved	<input type="checkbox"/>	Resolved with sequelae
<input type="checkbox"/>	Required new or prolonged hospitalisation	<input type="checkbox"/>	Resulted in persistent or significant disability/incapacity	<input type="checkbox"/>	Persisting	<input type="checkbox"/>	Worsened
<input type="checkbox"/>	Resulted in congenital anomaly/birth defect	<input type="checkbox"/>	Other (specify) _____	<input type="checkbox"/>	Fatal	<input type="checkbox"/>	Not assessable

SAE Assessment					
Study Treatment	Relationship to event <i>(Enter one code only)</i>	Event expected for the treatment <i>(Enter one code only)</i>	Action taken <i>(Enter one code only)</i>	Provide reason for action taken	
	0 = None 1 = Unlikely 2 = Possibly 3 = Probably 4 = Definitely	1 = Expected 2 = Not Expected	0 = None 1 = increased SpO ₂ range 2 = decreased SpO ₂ range 3 = Treatment permanently stopped		
SpO ₂ target:	<input type="checkbox"/> >94% <input type="checkbox"/> 88-92%	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Signature: <small>PI or other delegated personnel only</small>		Print name:		Date of report:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>d d m m y y</small>
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Office use only						
Checked by	Print name:		Signature:		Date:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>d d m m y y</small>
Reviewed by	Print name:		Signature:		Date:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <small>d d m m y y</small>