

<b>SAE</b>
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### 1. Study Information

<b>Study Title</b>	Fluids Exclusively Enteral from Day 1 (FEED1)				
<b>Sponsor ref. no</b>	DHRD/2018/116	<b>EudraCT no</b>	n/a	<b>NCTU ref. no</b>	1704

### 2. Site Information

<b>Site Name/Number</b>		<b>Country</b>	UK
<b>Name of person reporting this SAE</b>			
<b>Contact details</b>	<b>Phone:</b>	<b>Email:</b>	

### 3. Type of report

<b>Initial</b>	<input type="checkbox"/>	<b>Follow-up</b>	<input type="checkbox"/>
<b>Date of Report</b>	dd-mmm-yyyy	<b>If follow-up report enter NCTU SAE reference number supplied for initial report</b>	

### 4. Infant Information

<b>Infants ID</b>			
<b>Mother's initials</b>		<b>Date of Birth</b>	dd-mmm-yyyy

### 5. Details of Event

<b>Event Name:</b> <i>SAE in medical terms (diagnosis if possible)</i>	
<b>Description of Event:</b> <i>Please provide any additional relevant information e.g. signs and symptoms and any relevant tests/results. <b>DO NOT</b> use abbreviations</i>	

Serious Criteria			Yes	No	
			Death	<input type="checkbox"/>	<input type="checkbox"/>
			Life-threatening	<input type="checkbox"/>	<input type="checkbox"/>
			Hospitalisation/prolongation of hospitalisation	<input type="checkbox"/>	<input type="checkbox"/>
			Persistent/significant disability or incapacity	<input type="checkbox"/>	<input type="checkbox"/>
			Congenital anomaly or birth defect	<input type="checkbox"/>	<input type="checkbox"/>
			Other significant medical event – specify	<input type="checkbox"/>	<input type="checkbox"/>
Date of onset of event	dd-mmm-yyyy	Date event met "Serious criteria"	dd-mmm-yyyy		

## 6. Relevant Infant Medical History

Does the infant have any <i>relevant</i> medical history?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Name of condition	Tick if ongoing	
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>

## 7. Event Outcome

Outcome of event (tick one box only)	<input type="checkbox"/> <b>Fatal</b> Give cause of death if known, in event description (above)	<b>Date of death: dd-mmm-yyyy</b>
	<input type="checkbox"/> <b>Recovered/Resolved without sequelae</b>	<b>Date of recovery: dd-mmm-yyyy</b>
	<input type="checkbox"/> <b>Recovered/Resolved with sequelae</b> describe in event description (above)	
	<input type="checkbox"/> <b>Ongoing</b> (ensure follow-up is sent when available)	
	<input type="checkbox"/> <b>Unknown at time of report</b> (ensure follow-up is sent as soon as possible)	

## 8. Cause of Event

<b>Cause of Event</b> (Detail all possible and suspected causes including relevant medical history)	
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### 9. Study intervention

<b>Has the infant started feeding prior to the time of this event?</b>	<input type="checkbox"/> <b>Yes</b>		<input type="checkbox"/> <b>No</b>		
<b>In the Investigator's opinion, is the SAE related to this study intervention?</b> (tick one only)	<b>Definitely related</b> <input type="checkbox"/>	<b>Probably related</b> <input type="checkbox"/>	<b>Possibly Related</b> <input type="checkbox"/>	<b>Unlikely to be related</b> <input type="checkbox"/>	<b>Unrelated</b> <input type="checkbox"/>
<b>Action taken as a result of this SAE</b>	<b>None</b> <input type="checkbox"/>	<b>Intervention temporarily discontinued</b> <input type="checkbox"/>	<b>Intervention permanently discontinued</b> <input type="checkbox"/>	<b>Other – specify:</b> <input type="checkbox"/>	

### 10. Additional Information

<b>Additional relevant information</b>	
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### 11. Completion Details

<b>Report Completed by (You must have signed the delegation log)</b>	Name:	Signature:	Date: dd-mmm-yyyy
<b>Investigator review (if not reporter) (You must have signed the delegation log)</b>	<i>By signing below I confirm the seriousness, causality and outcome of this report</i>		
	Name:	Signature:	Date: dd-mmm-yyyy

### For NCTU/Sponsor Use Only

### 12. Clinical Evaluation (Medical Monitor/Chief investigator)

<b>Causality Assessment:</b>	<input type="checkbox"/> <b>Unrelated</b>		
	<input type="checkbox"/> <b>Related</b>	<b>Expectedness Assessment:</b> Only required if "related"	
		<input type="checkbox"/> <b>Expected</b>	<input type="checkbox"/> <b>Unexpected*</b>

<b>Assessment completed by:</b>	Name:	Signature:	Date: dd-mmm-yyyy
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\*SAEs that are considered to be related to trial intervention and are unexpected (as per the current trial-specific Reference Safety Information) are subject to expedited reporting to the MHRA and/or REC.