| SAE |
|---|

## 1. Study Information

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

## 2. Site Information

| | | | |
|---|---|---|---|
| **Site Name/Number** | | **Country** | **UK** |
| **Name of person reporting this SAE** | | | |
| **Contact details** | **Phone:** | **Email:** | |

## 3. Type of report

| | | | |
|---|---|---|---|
| **Initial** | ☐ | **Follow-up** | ☐ |
| **Date of Report** | dd-mmm-yyyy | **If follow-up report enter NCTU SAE reference number supplied for initial report** | |

## 4. Infant Information

| | | | |
|---|---|---|---|
| **Infants ID** | | **Date of Birth (Infant)** | **dd-mmm-yyyy** |
| **Mother's initials** | | **Date of Birth (Mother)** | **dd-mmm-yyyy** |

## 5. Details of Event

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

| Serious Criteria | | | Yes | No |
|---|---|---|---|---|
| | Death | | ☐ | ☐ |
| | Life-threatening | | ☐ | ☐ |
| | Hospitalisation/prolongation of hospitalisation | | ☐ | ☐ |
| | Persistent/significant disability or incapacity | | ☐ | ☐ |
| | Congenital anomaly or birth defect | | ☐ | ☐ |
| | Other significant medical event – specify _____ | | ☐ | ☐ |
| **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 *relevant* medical history?** | ☐ **Yes** | ☐ **No** |
|---|---|---|
| **Name of condition** | **Tick if ongoing** | |
| | ☐ | |
| | ☐ | |
| | ☐ | |
| | ☐ | |
| | ☐ | |

## 7. Event Outcome

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

## 8. Cause of Event

| | |
|---|---|
| **Cause of Event** (Detail all possible and suspected causes including relevant medical history) | |

## 9. Study intervention

| | | | | | |
|---|---|---|---|---|---|
| **Has the infant started feeding prior to the time of this event?** | ☐ **Yes** | | ☐ **No** | | |
| **In the Investigator's opinion, is the SAE related to this study intervention?** (tick one only) | **Definitely related** ☐ | **Probably related** ☐ | **Possibly Related** ☐ | **Unlikely to be related** ☐ | **Unrelated** ☐ |
| **Action taken as a result of this SAE** | **None** ☐ | **Intervention temporarily discontinued** ☐ | **Intervention permanently discontinued** ☐ | **Other – specify:** ☐ | |

## 10. Additional Information

| | |
|---|---|
| **Additional relevant information** | |

## 11. Completion Details

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

***For NCTU/Sponsor Use Only***

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

| | | | |
|---|---|---|---|
| **Causality Assessment:** | ☐ **Unrelated** | | |
| | ☐ **Related** | **Expectedness Assessment:** Only required if "related" | |
| | | ☐ **Expected** | ☐ **Unexpected*** |

| | | | |
|---|---|---|---|
| **Assessment completed by:** | Name: | Signature: | Date: dd-mmm-yyyy |

**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.*