COLLABORATE Serious Adverse Reaction Form

The safety reporting window for this trial is from randomisation (1 or 2) until 34 weeks PMA, discharge from neonatal care, or death, whichever is sooner. All expected SARs have been listed as study endpoints, these events will be excluded from safety reporting. As justified in the study protocol, only Unexpected and Related SARs require reporting.

Please report SARs directly into the SAR form on OpenClinica. If access to OpenClinica is unavailable, please report the relevant details below, and then transcribe onto OpenClinica when available. This form should act as a temporary transcription aid only.

For reporting procedures and timelines please refer to the safety reporting manual.

Site Name	
Site Number	
Participant Trial ID	
Date of randomisation to R1 (if applicable)	
Date of randomisation to R2 (if applicable)	
SAR Number	
Type of Report	☐First ☐ Interim ☐ Final
Why was the event serious?	☐Resulted in death ☐ Life-threatening ☐ Required inpatient hospitalisation or prolongation of existing hospitalisation ☐ Resulted in persistent or significant disability/incapacity ☐ Other medically important event (please provide details) _____
Details of SAR	
Serious Adverse Reaction Term	
Briefly describe SAR *(Include relevant symptoms, body site, lab tests and treatments received for management of the SAE)*	
Date of Notification	

Date of Onset	
Severity	☐ Mild ☐ Moderate ☐ Severe ☐ Life threatening or disabling ☐ Fatal
Outcome	☐ Resolved ☐ Resolved with Sequelae ☐ Persisting ☐ Worsened ☐ Fatal ☐ Not assessable
Date of Outcome	
Relationship to study intervention (Donor milk supplement vs Formula supplement) R1 Only related events are required to be reported	☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Not related ☐ Not assessable *Leave blank if participant is not taking part in R1*
Relationship to study intervention (Routine fortification vs No routine fortification) R2 Only related events are required to be reported	☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Not related ☐ Not assessable *Leave blank if participant is not taking part in R2*
Is the event expected in line with the study endpoints?	☐ Expected ☐ Unexpected
Action Taken	☐ None ☐ Intervention Reduction ☐ Intervention Delayed ☐ Intervention Delayed and Reduced ☐ Intervention Permanently Stopped
Form completed by (Name, role)	
Date	
PI Assessment (to be completed by PI only)	
Assessment of the implications, if any, for	

the safety of study participants	
How will these be addressed	
PI name and signature	
Date	
CI review (to be completed by CI only)	
Expectedness	☐ Expected ☐ Unexpected
Relationship to study intervention (Donor milk supplement vs Formula supplement) <u>Only related events are required to be reported</u> *Leave blank if participant is not taking part in R1*	☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Not related ☐ Not assessable
Relationship to study intervention (Routine fortification vs No routine fortification) <u>Only related events are required to be reported</u> *Leave blank if participant is not taking part in R2*	☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Not related ☐ Not assessable
Comments	
CI name and signature	
Date	