Lactoferrin or placebo should continue until the infant has reached 34 week’s postmenstrual age. Data collection should continue until discharge to home or death, except in the case of permanent discontinuation of intervention (see below).

Intervention period completed

- At the completion of the intervention (when the infant has reached 34 weeks’ postmenstrual age), please discontinue Form 2: Daily Dosing Log but continue data collection for all Form 3: Late-Onset Invasive Infection and/or Form 4: Gut Signs as necessary until the infant is discharged home, transferred to another unit, or has died (see Guidance Sheet 4 - Completion of Data Collection Forms).
- Form 5: Hospital Transfer/Discharge should be completed and returned when the infant is discharged home, transferred to another unit, or has died.

Infant death

- If an infant dies before being discharged from hospital, complete a Form 5: Hospital Transfer/Discharge covering the period that the infant was an inpatient in your unit. If there were any episodes of late-onset invasive infection or gut signs during this period, ensure that a Form 3: Late-Onset Invasive and/or Form 4: Gut Signs is completed for each episode and the originals returned with the Form 5 to the ELFIN Coordinating Centre.
- In addition please send an anonymised copy of the discharge summary and, if and when available, an anonymised copy of the post-mortem examination report. Please remember to add the study number.

Parent request to withdrawal from the trial

- A parent has the right to withdraw their infant from the trial at any time and for any reason, without prejudice to the infant’s care; they do not have to provide a reason for their decision.
- It is important that you clarify with the parent(s) whether, despite stopping the intervention, they permit retention and use of data already collected and/or data collection to continue to completion.
- After consulting the parents complete Form 6: Discontinuation of Intervention recording their wishes regarding the withdrawal. Please make two photocopies of the completed Form 6 and file one in the infant’s clinical notes and the second in the ELFIN Data Collection File. Send the original to the ELFIN Coordinating Centre.

Clinician decision to stop the intervention permanently prior to 34 postmenstrual weeks

- There will be very few instances where the clinician will need to permanently discontinue lactoferrin or placebo. It will be far more common to temporarily discontinue for clinical reasons and restart when it is deemed safe to do so.
- If the allocated intervention is permanently discontinued by the clinician, please complete a Form 6: Discontinuation of Intervention. The infant remains in the trial and you should complete data collection procedures as normal.
Accountability

Accountability of IMP use is in accordance with Good Clinical Practice for a CTIMP. Form 2: Daily Dosing Log includes columns to account for used and unused containers. The accountability columns must be completed before the form is returned to the ELFIN Coordinating Centre in order for the site stock balance to be reconciled and destruction of unused IMP authorised.

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Infant receiving lactoferrin or placebo

34 postmenstrual weeks reached

- Continue data collection until at discharge to home or death

Discontinuation of intervention

- Clinician decision
  - Complete Form 6: Discontinuation of Intervention and place a copy in the infant’s clinical notes
  - Continue to collect data until at discharge to home or death

- Parent request
  - Complete Form 6: Discontinuation of Intervention and place a copy in the infant’s clinical notes
  - Have the parents agreed that we can continue to collect clinical data until the infant is discharged from hospital?
    - YES
      - Continue to collect data until at discharge to home or death
    - NO
      - Discontinue data collection

Infant death

- Complete Form 5: Hospital transfer & Discharge and return to the ELFIN Coordinating Centre with all Form 3: Late-Onset Invasive Infection and Form 4: Gut Signs (if relevant)
  - Send the ELFIN Coordinating Centre an anonymised copy of the discharge summary
  - If available, send the ELFIN Coordinating Centre an anonymised copy of the post-mortem examination report

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1 Permanent discontinuation of intervention before the infant has reached 34 postmenstrual weeks
2 Parental request to either permanently discontinue the intervention or completely withdraw their infant from the trial.