

NIHR National Institute for Health Research

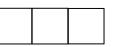




eCRF Paper Workbook

This workbook is to be used as an aide memoire only, it does not replace the electronic CRF (MACRO). All paper workbooks and additional forms should be retained in the Investigator Site File as they represent Source Data.

Mother's Initials:



(If only two initials are given then please separate with a hyphen)

Infant ID:

	-	
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Sponsor: University Hospitals of Derby and Burton NHS Foundation Trust

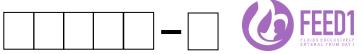
CRF Version: Final Version 1.3

PLEASE ATTACH ANY ADDITIONAL FORMS TO THIS WORKBOOK

This includes the following forms: Late-Onset Infection, Gut Signs, Daily data collection (aide memoire) and SAEs

Mother'	's In	itials	5
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This workbook has been produced to assist with the data collection for the FEED1 trial.

Please ensure that data collected using this workbook is entered into the electronic CRF (MACRO) within 7 days of being collected, where possible.

The electronic CRF can be found at the below link:

https://macro02.nottingham.ac.uk/

Should any of the below additional forms be used for this infant, please attach them to this workbook.

- Daily data collection
- Gut signs
- Late-onset infection
- Serious Adverse Event (SAE) reporting form

The original copies of all CRF workbooks and additional forms must be kept in a secure location.

Should you have any queries regarding the data collection process, please contact the trial coordinating centre:

Email: feed1@nottingham.ac.uk

Telephone: 0115 82 31592

Mother's Initials:		Infant ID:]—	G	FEED1
				_		

	Neonatal	
Was this infant delivered via caesarean section?	Yes 🗆 No 🗆	
Were the membranes ruptured >24 hours before delivery?	Yes 🗆 No 🗆	
Was this infant's heart rate >100 bpm at 5 minutes of age?	Yes 🗆 No 🗆	
What was this infant's temperature when first admitted to the first neonatal unit? (°C)		
What was this infant's worst base excess measured within 24 hours of birth?	Please indicate if this was a positive or negative value • • • Positive □ Negative □	
Was this infant receiving respiratory support at the time of randomisation?	Yes 🗆 No 🗆	
If yes, select support (Tick all that apply)	Mechanical ventilation	
	CPAP 🗆	
	Heated humidified flow nasal cannula therapy \Box	
	Any other supplemental oxygen 🛛	

Mother's	Initials:



Infant ID:



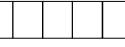
		Daily f	eed log (da	ay 1-7)			
Feeding	allocation				Full m	ilk feed 🛛	
(as per rand	omisation)	Gradual milk feed					
Day	1	2	3	4	5	6	7
Date (dd-mmm-yyyy)	dd- mmm- yyyy	dd- mmm- УУУУУ	dd- mmm- yyyy	dd- mmm- yyyy	dd- mmm- УУУУ	dd- mmm- yyyy	dd- mmm- УУУУ
Complete the weigh	t (in g) use	d to calcul	ate the vol	ume of flui	ds/feeds g	iven today	
Weight (g) used to calculate the volume of fluids/feeds given?							
Enteral Feeds							
Total milk feed volume received per day (ml)							
Complete the volum	e (in ml) of	f each type	e of milk pe	r day (ente	er 0 if no mil	k given)	
Expressed Mother's breast milk							
Human donor milk							
Preterm formula milk							
Term formula milk							
Was breast milk fortifier added to any breast milk today	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □
Was the baby breast fed today?	Yes* □ No □	Yes* □ No □	Yes* □ No □	Yes* □ No □	Yes* □ No □	Yes* □ No □	Yes* □ No □
*For breast fed babies, where milk volume is unknown, is the baby considered fully fed today by combination of breast/bottle?	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □
Did the infant receive IV fluids on this day?	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □
Did the infant received parenteral nutrition on this day	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □
How many hours of IV fluids and/or parenteral nutrition did the infant have on this day? (Excluding any fluid infusion used for maintaining venous line patency or infusions via arterial lines)							d overloof

Continued overleaf

-		Infa					ENTER			
Day	1	2	3	4	5	6	7			
Antibiotic and Antifungal (excluding prophylatic antifungal treatment) information										
Date (dd-mmm-yyyy)	dd- mmm- yyyy	dd- mmm- yyyy	dd- mmm- yyyy	dd- mmm- yyyy	dd- mmm- yyyy	dd- mmm- yyyy	dd- mmm- yyyy			
Were antibiotics/ antifungals given on this day?	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □			
<i>Please complete ((72 hours after b</i>							ticked			
Were feeds stopped or withheld for more than 4 hours on this day?	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □	Yes □ No □			
Please complete a from suspected N		s form if 5	consecutiv	e days are	ticked or i	if this infar	nt died			
Cannula Informat This includes all the Intravenous fluid o	e new intrav		ulas that wo	ere inserted	today and v	were used t	o give any			
This includes all the Intravenous fluid o Is there an IV cannula in today? *How many new cannulas inserted	e new intrav		ulas that we Yes* no	ere inserted Yes* 🗆 no 🗆	today and v Yes* no	were used to Yes* no	o give any Yes* □ no □			
This includes all the	e new intrav r medication Yes* no	n Yes* □ no □	Yes* 🗆	Yes* 🗆	Yes* 🗆	Yes* 🗆	Yes* 🗆			
This includes all the Intravenous fluid o Is there an IV cannula in today? *How many new cannulas inserted today	e new intrav r medication Yes* no	n Yes* □ no □	Yes* 🗆	Yes* 🗆	Yes* 🗆	Yes* 🗆	Yes* 🗆			
This includes all the Intravenous fluid o Is there an IV cannula in today? *How many new cannulas inserted today Central venous lin Is there a central venous line in today <i>(including</i> <i>UVC/ longline/</i>	e new intrav r medication Yes* no ne Informa Yes*	n Yes* □ no □ ation Yes* □	Yes* □ no □ Yes* □	Yes* □ no □ Yes* □	Yes*	Yes* □ no □ Yes* □	Yes* 🗆			
This includes all the Intravenous fluid o Is there an IV cannula in today? *How many new cannulas inserted today Central venous lin Is there a central venous line in today (including UVC/ longline/ surgical lines)? *How many were inserted today?	e new intrav r medication Yes* no ne Informa Yes* no	n Yes* □ no □ ation Yes* □	Yes* □ no □ Yes* □	Yes* □ no □ Yes* □	Yes*	Yes* □ no □ Yes* □	Yes* 🗆			
This includes all the Intravenous fluid o Is there an IV cannula in today? *How many new cannulas inserted today Central venous lin Is there a central venous line in today (including UVC/ longline/ surgical lines)? *How many were	e new intrav r medication Yes* no ne Informa Yes* no	n Yes* □ no □ ation Yes* □	Yes* □ no □ Yes* □	Yes* □ no □ Yes* □	Yes*	Yes* □ no □ Yes* □	Yes* 🗆			









Daily feed log (day 8-14)							
Feeding	allocation				Full m	ilk feed 🛛	
(as per rand	omisation)				Gradual m	ilk feed 🛛	
Day	8	9	10	11	12	13	14
Date (dd-mmm-yyyy)	dd- mmm- yyyy						
Complete the weight	t (in g) use	d to calcul	ate the vol	ume of flui	ds/feeds g	iven today	
Weight (g) used to calculate the volume of fluids/feeds given?							
Enteral Feeds							
Total milk feed volume received per day (ml)							
Complete the volum	e (in ml) of	f each type	of milk pe	r day (ente	er 0 if no mil	k given)	
Expressed Mother's breast milk							
Human donor milk							
Preterm formula milk							
Term formula milk							
Was breast milk fortifier added to any breast milk today	Yes □ No □						
Was the baby breast fed today?	Yes* □ No □						
*For breast fed babies, where milk volume is unknown, is the baby considered fully fed today by combination of breast/bottle?	Yes □ No □						
Did the infant receive IV fluids on this day?	Yes □ No □						
Did the infant received parenteral nutrition on this day	Yes □ No □						
How many hours of IV fluids and/or parenteral nutrition did the infant have on this day? (Excluding any fluid infusion used for maintaining venous line patency or infusions via arterial lines) Continued overleaf							

Mother's Initials:		Infant	ID:				FEED1
Day	8	9	10	11	12	13	14
Antibiotic and Antifu	ıngal (exclı	uding prop	hylatic ant	ifungal trea	<i>atment)</i> inf	ormation	
Date (dd-mmm-yyyy)	dd- mmm- yyyy						
Were antibiotics/ antifungals given on this day?	Yes □ No □						
Please complete a La hours after birth) or							ed (72
Were feeds stopped or withheld for more than 4 hours on this day?	Yes □ No □						
Please complete a G suspected NEC	ut signs fo	rm if 5 con	secutive da	iys are tick	ed or if thi	s infant die	d from
Cannula Information This includes all the ne Intravenous fluid or m	ew intraveno	us cannulas	that were in	nserted toda	y and were	used to give	e any
Is there an IV cannula in today?	Yes* □ no □						
*How many new cannulas inserted today							
Central venous line	Informatio	n					
Is there a central venous line in today (including UVC/ longline/ surgical lines)?	Yes* □ no □						
*How many were inserted today?							
Hypoglycemia Infor	mation						
Number of times Blood glucose tested today?							
Was the Blood glucose test result(s) <2.2 mmol/L	Yes* □ no □						
*If yes please complet	e a Hypogly	cemia form	(see page 1	0 of this wo	rkbook)		

Infant ID:

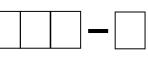




		Daily fe	ed log (day	/ 15-21)			
Feeding allocation Full milk feed							
(as per rand	omisation)	Gradual milk feed 🛛					
Day	15	16	17	18	19	20	21
Date (dd-mmm-yyyy)	dd- mmm- yyyy						
Complete the weigh	t (in g) use	ed to calcul	ate the vol	ume of flui	ds/feeds g	iven today	
Weight (g) used to calculate the volume of fluids/feeds given today?							
Enteral Feeds							
Total milk feed volume received per day (ml)							
Complete the volum	e (in ml) o	f each type	e of milk pe	r day (ente	er 0 if no mil	lk given)	
Expressed Mother's breast milk							
Human donor milk							
Preterm formula milk							
Term formula milk							
Was breast milk fortifier added to any breast milk today	Yes □ No □						
Was the baby breast fed today?	Yes* □ No □						
*For breast fed babies, where milk volume is unknown, is the baby considered fully fed today by combination of breast/bottle?	Yes □ No □						
Did the infant receive IV fluids on this day?	Yes □ No □						
Did the infant received parenteral nutrition on this day	Yes □ No □						
How many hours of IV fluids and/or parenteral nutrition did the infant have on this day? (Excluding any fluid infusion used for maintaining venous line patency or infusions via arterial lines)						Continue	

Continued overleaf

Mother's Initials:		Infant	ID:				FEED1 FLUIDS EXCLUSIVELY ENTERAL FROM DAY		
Day	15	16	17	18	19	20	21		
Antibiotic and Antifungal (excluding prophylatic antifungal treatment) information									
Date (dd-mmm-yyyy)	dd- mmm- УУУУ	dd- mmm- yyyy	dd- mmm- yyyy	dd- mmm- yyyy	dd- mmm- yyyy	dd- mmm- yyyy	dd- mmm- yyyy		
Were antibiotics/ antifungals given on this day?	Yes □ No □								
Please complete a L hours after birth) or							ed (72		
Were feeds stopped or withheld for more than 4 hours on this day?	Yes □ No □								
Please complete a G suspected NEC	ut signs fo	rm if 5 con	secutive da	ays are tick	ed or if thi	s infant die	ed from		
Cannula Information This includes all the ne Intravenous fluid or m	ew intravend	ous cannulas	s that were i	nserted toda	ay and were	used to give	e any		
Is there an IV cannula in today?	Yes* □ no □								
*How many new cannulas inserted today									
Central venous line	Informatio	n							
Is there a central venous line in today (including UVC/ longline/ surgical lines)?	Yes* □ no □								
*How many were inserted today?									
Hypoglycemia Infor	mation								
Number of times Blood glucose tested today?									
Was the Blood glucose test result(s) <2.2 mmol/L	Yes* □ no □								
*If yes please complet	e a Hypogly	cemia form	(see page 1	0 of this wo	rkbook)				





Clinically Appropriate Alterations from Allocated Feeding Regime

FEED1 feeding protocol:

Full milk: infant is expected to have a total of \leq 24hours IV fluids/parenteral nutrition from birth to achieving full feeds.

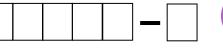
Gradual milk: infant is expected to have a total of >24hours IV fluids/parenteral nutrition from birth to achieving full feeds.

Did the infant's <i>actual</i> feeding regime meet the above <i>expected</i> criteria?	□ Yes □ No*
*Please state the <u>main</u> reason for altering from the allocated feeding regime	 Parental choice Not tolerating feeds (e.g. vomiting, large aspirates) Hypoglacemia, needing IV glucose Escalation of respiratory support (inc. needing mechanical ventilation) Abdominal concerns, including suspected NEC Other clinical deterioration Unable to get IV access Other *
*please specify	

	Hypoglycaemia details	
Please enter details for Blood gl	lucose results <2.2 mmol/L	
Date (dd-mmm-yyyy)	Time (hh:mm)	Value

Mother's	Initials:
i lotifei 5	minutary.

Infant	ID:





Discharge Home		
<u>home</u> . This form should not be completed away whilst in your hospital. For infants	npleted once for each infant, at the point in which they are transferred I at the time an infant is transferred to a different hospital or has passed who have been transferred to another hospital, you should liaise with rnet (or similar) to ensure that this information is entered at the time of	
Date of discharge home		
(dd-mmm-yyyy)		
Weight at discharge home (g)		
Date infant first regained birth weight (dd-mmm-yyyy)		
Head circumference at discharge home (cm)		
Was length of infant measured at discharge home?	Yes* 🗆 No 🗆	
*Length of infant i.e. crown to heel at discharge home (cm)		
Modes of feeding at discharge	Breast feeding 🛛	
home: (please tick all that apply)	Cup feeding	
	Bottle feeding 🛛	
	Nasogastric tube 🛛	
	Gastrostomy tube □	
	Types of feeding	
Types of milk for feeding at discharge home: (please tick all	Breast fed on demand	
that apply)	Expressed Mothers breast milk \Box	
	Human donor milk	
	Preterm formula milk 🛛	
	Term formula milk 🛛	
	Hydrolysed formula milk or lactose free formula milk (e.g. Enfamil, Nutramigen, Pepti junior)	
	Amino acid-based formula milk (e.g. Neocate, PureAmino) 🛛	

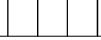
Mother's Initials:		Infant ID:	
		Term formula milk with increased energy (other than preterm formula) (e.g. SMA high energy or Infatrini)	
		Other*	
*If other, please s	specify		
Please specify the at discharge home	type of formula	Nutriprem 1	
		Nutriprem 2	
		Neocate	
		Nutramigen	
		Pepti Junior	
		Infatrini	
		SMA High Energy	
		Aptamil First milk	
		Cow and Gate First Infant Milk	
		SMA First Infant Milk	
		Enfamil A.R.	
		Aptamil Preterm	
		SMA Gold Prem 1	
		SMA Gold Prem 2	
		Aptamil Pepti 1	
		Aptamil Pepti 2	

Mother's Initials:	Infant ID:
	Pregestimil 🛛
	Caprilon 🗆
	Wysoy 🗆
	Infasoy 🗆
	SMA Breast Milk Fortifier 🛛
	Cow and Gate Nutriprem Milk Fortifier
	Other*
*If other, please specify	
Please tick if Breast milk fortifier is being used at discharge home	Breast milk fortifier 🛛
Please state the number of days Parental nutrition was received in this admission	
Please state the number of days central lines were used in this admission	
D	ischarge Home (Continued)
Please state the number of central venous lines inserted in this admission (including umbilical and percutaneous or surgically inserted venous lines)	
While in this unit during this adm (HRG = Health Resource Group) If no days were in one of the following	nission, how many days did this infant receive:
Intensive Care (HRG XA01Z)	
High Dependency Care (HRG XA02Z)	
Special Care (HRG XA03Z)	
Special Care with Primary Carer Resident or Transitional Care (HRG XA04Z)	

Mother's	Initials:

Infant	IC
mane	

D:





Were any of the following diagnosed	during this infant's stay in the u	nit?		
Retinopathy of prematurity treated medically or surgically	Yes*		No 🗆	
*If yes,			Laser 🗆	
			Cryotherapy 🗆	
	۵	۸nti-V	'EGF Injection □	
Bronchopulmonary dysplasia; mechanical ventilator support via endotracheal tube or nasal CPAP at 36 weeks PMA; or supplemental oxygen at 36 weeks PMA	Yes		No 🗆	
Intracranial abnormality:	Yes*		No 🗆	
*If yes	Grade1 IVH/Germinal Ma	atrix	Haemorrhage 🗆	
			Grade 2 IVH	
			H (distension)	
Devision trisulan la devisa ma la sia d	Grade 4 IVH (parench	ymal	involvement)	
Periventricular leukomalacia:	Yes		No 🗆	
Shunt for hydrocephalus:	Yes		No 🗆	
Late onset invasive infection	Yes*		No 🗆	
*If yes, please ensure Late onset Invasive infection form has been completed for each episode				
Necrotising enterocolitis (Bell stage 2 or 3)	Yes*		No 🗆	
*If yes, please ensure that a Gut Signs Form has been completed for each episode				

Mother's Initials: Discharge criteria definitions	Infant ID:
Weight:	Date when infant reached \geq 1700g Please note, if the infant has not reached 1700g prior to discharge, it may be possible to obtain this date from BadgerNet or the home care team.
Feeding:	Date when infant was able to take at least one full suck feed in the last 24 hours
Temperature control:	Date when infant maintained body temperature without additional temperature support for at least 24 hours
Date when all 3 of the discharge criteria as per the definitions above were first met (dd-mmm-yyyy)	

Following hospital discharge please check that the following details have been added to the Randomisation database:-

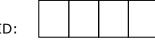
- Infant's name and NHS number
- Mother's demographic questions have been completed
- Written Informed consent, if on the Oral assent pathway has been collected.

							13	FEED1
Mother's Initials:		Infant ID:					e	FLUIDS EXCLUSIVELY ENTERAL FROM DAY 1

Transfer 1							
Infant Transferred to another ho	Infant Transferred to another hospital						
Name of Hospital							
Town of Hospital							
Name of receiving consultant (if known)							
Date of transfer (dd-mmm-yyyy)							

Transfer 2							
Infant Transferred to another ho	Infant Transferred to another hospital						
Name of Hospital							
Town of Hospital							
Name of receiving consultant (if known)							
Date of transfer (dd-mmm-yyyy)							

Transfer 3							
Infant Transferred to another ho	Infant Transferred to another hospital						
Name of Hospital							
Town of Hospital							
Name of receiving consultant (if known)							
Date of transfer (dd-mmm-yyyy)							





Protocol Deviations

Please enter any protocol deviations directly into the electronic CRF.

Death						
Has the Infant died?	Yes 🗆 No 🗆	1				
Date of death (dd-mmm-yyyy)						
Primary cause of Death						
Secondary cause of Death						

Cessation/discontinuation of trial activities							
<i>Please use the below form to report infants who have discontinued</i> <u>ANY</u> <i>trial related activity but who have not withdrawn (e.g. happy to provide routine data but do not wish to be contacted for 6-week follow-up):</i>							
Has the decision been made for the infant to discontinue	Yes 🗆						
from <u>ANY</u> trial activities?	No 🗆						
*If yes, please state discontinuation type (tick any activity that the infant WILL NO LONGER participate in)	Provision of routine data 6-week Follow-up questionnaire and reminders Study results communications Contact for future studies Contact for future studies Contact for follow-up in early childhood						
Date of Discontinuation (dd-mmm-yyyy)							
Reason for discontinuation							

Mother's Initials:		Infant ID:			—		C	FEED1
						J		ENTERAL FROM DATT

Withdrawal of Infant								
Please use the below table to rep	Please use the below table to report only infants who have withdrawn from <u>ALL</u> trial-related activity							
Has the participant withdrawn	Yes 🗆							
from <u>ALL</u> trial-related activities?	No 🗆							
Date of withdrawal (dd-mmm-yyyy)								
Reason for withdrawal	Mother withdrew infant \Box							
	Clinician Decision							
	Other* 🗆							
*please specify								

Please note the PI will be required to login to Macro database to review and sign off each CRF once all data has been completed, the NCTU will contact site when this can be done.