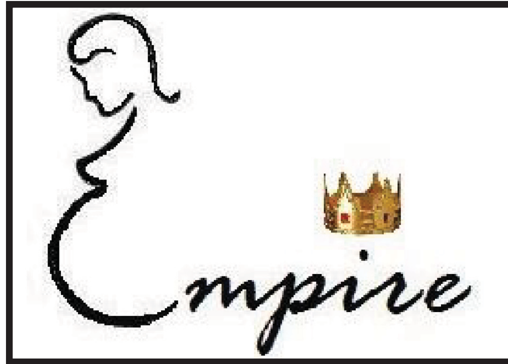

POSTNATAL FOLLOW-UP BOOKLET

Patient UTIN: __ __/__ __ __

POSTNATAL FOLLOW-UP BOOKLET	Visit checklist	Participant UTIN	Visit date
		__/___	DD / MMM / YYYY

CHECKLIST		ACTION
Has a blood sample been taken?	**Yes** ☐	Send EMPIRE trial blood request form to trial office Centrifuge and package sample according to SOP no.3 Blood collection and processing
	No ☐	Centrifuge and package sample according to SOP no.3 Blood collection and processing Send EMPIRE trial blood request form to trial office Or Document reason why blood sample was not taken. ***Please state here:***
Has the participant completed: **Patient's questionnaire?**	**Yes** ☐	Return completed **Patient's questionnaire** to participant's CRF file.
	No ☐	Ask participant to complete **Patient's questionnaire** and file in participant's CRF file. OR Document reason why not completed ***Please state here:***
Have there been any dose changes to AED or concomitant medication?	**Yes** ☐	Please, if so note all the changes in relevant part of this booklet.
	No ☐	No further action
Has participant experienced any adverse events?	**Yes**	Report in accordance with SOP no. 4. Adverse events and serious adverse events reporting. Update **Adverse Events Form**.
	No	No further action

POSTNATAL FOLLOW-UP BOOKLET	Post Natal Form	Participant UTIN	Visit date
		_ _/_ _ _	DD / MMM / YYYY

Please use the following sheets to document information about all of the participant's births/children. One sheet should be used per child. Please specify child number between booklet name and participant UTIN.

NEONATAL DEATH

Neonatal death	**Yes** ☐ **No** ☐		
Date of neonatal death	DD / MMM / YYYY		
Reasons for neonatal death *(please tick all relevant reasons)*	**Congenital abnormalities**		☐
	Infection		☐
	Birth trauma		☐
	Extreme prematurity		☐
	Other	*If **other**, please specify:*	☐

BABY DETAILS

Age (n/52)		**Weight**	kg	**Head Circumference**	cm
Any maternal concerns	**Yes** ☐ **No** ☐ *If **yes**, please specify below:*				
Admission to neonatal unit after discharge	**Yes** ☐ **No** ☐ *If **yes**, please specify below:*				
Baby has been in neonatal unit since birth	**Yes** ☐ **No** ☐	**Baby has congenital abnormalities**	**Yes** ☐ **No** ☐		

BREASTFEEDING

Current feeding method		**Duration of sole breastfeeding**
Sole breast feeding	☐	
Mixed breast & bottle	☐	Weeks________ Days__________
Bottle only	☐	Weeks________ Days__________

POSTNATAL FOLLOW-UP BOOKLET	Post Natal Form	Participant UTIN	Visit date
		__/___	DD / MMM / YYYY

Please use the following sheets to document information about all of the participant's births/children. One sheet should be used per child. Please specify child number between booklet name and participant UTIN.

NEONATAL DEATH

Neonatal death	Yes ☐ No ☐		
Date of neonatal death	DD / MMM / YYYY		
Reasons for neonatal death *(please tick all relevant reasons)*	Congenital abnormalities		☐
	Infection		☐
	Birth trauma		☐
	Extreme prematurity		☐
	Other	Please specify:	☐

BABY DETAILS

Age (n/52)		Weight	kg	Head Circumference	cm
Any maternal concerns	Yes ☐ No ☐ *If **yes**, please specify*				
Admission to neonatal unit after discharge	Yes ☐ No ☐ *If **yes**, please specify*				
Baby has been in neonatal unit since birth	Yes ☐ No ☐				
Baby has congenital abnormalities	Yes ☐ No ☐				

BREASTFEEDING

Current feeding method		Duration of sole breastfeeding
Sole breast feeding	☐	
Mixed breast & bottle	☐	Weeks________ Days__________
Bottle only	☐	Weeks________ Days__________

POSTNATAL FOLLOW-UP BOOKLET	Post Natal Form	Participant UTIN	Visit date
		__ __/__ __ __	DD / MMM / YYYY

Please use the following sheets to document information about all of the participant's births/children. One sheet should be used per child. Please specify child number between booklet name and participant UTIN.

NEONATAL DEATH

Neonatal death	**Yes** ☐ **No** ☐		
Date of neonatal death	DD / MMM / YYYY		
Reasons for neonatal death *(please tick all relevant reasons)*	**Congenital abnormalities**		☐
	Infection		☐
	Birth trauma		☐
	Extreme prematurity		☐
	Other	**Please specify:**	☐

BABY DETAILS

Age (n/52)		**Weight**	kg	**Head Circumference**	cm
Any maternal concerns	**Yes** ☐ **No** ☐ *If **yes**, please specify*				
Admission to neonatal unit after discharge	**Yes** ☐ **No** ☐ *If **yes**, please specify*				
Baby has been in neonatal unit since birth	**Yes** ☐ **No** ☐				
Baby has congenital abnormalities	**Yes** ☐ **No** ☐				

BREASTFEEDING

Current feeding method		**Duration of sole breastfeeding**
Sole breast feeding	☐	
Mixed breast & bottle	☐	Weeks________ Days___________
Bottle only	☐	Weeks________ Days___________

POSTNATAL FOLLOW-UP BOOKLET	Adherence checklist Part 1	Participant UTIN	Visit date
		__ __/__ __ __	DD / MMM / YYYY

CURRENT AED

Current AED Please use Brand name, if prescribed		Current daily dose (mg)	Date of any dose change after delivery
carbamazepine (generic)	Yes ☐ No ☐		DD / MMM / YY
Tegretol	Yes ☐ No ☐		DD / MMM / YY
Tegretol Retard	Yes ☐ No ☐		DD / MMM / YY
lamotrigine (generic)	Yes ☐ No ☐		DD / MMM / YY
Lamictal (brand)	Yes ☐ No ☐		DD / MMM / YY
levetiracetam (generic)	Yes ☐ No ☐		DD / MMM / YY
Keppra (brand)	Yes ☐ No ☐		DD / MMM / YY
phenytoin (generic)	Yes ☐ No ☐		DD / MMM / YY
Epanutin (brand)	Yes ☐ No ☐		DD / MMM / YY
sodium valproate (generic)	Yes ☐ No ☐		DD / MMM / YY
Epilim (brand)	Yes ☐ No ☐		DD / MMM / YY

Has there been an AED dose change since delivery?	**Yes** ☐ **No** ☐
If the dose has been changed since delivery:	
1) Who was responsible for the change:	**Clinician** ☐ **Patient** ☐
2) Was it in response to: *(please tick all relevant reasons)*	**Routine clinical plan** ☐ **Patient concerns** ☐ **Clinician concerns** ☐

Has the patient taken the AED postnatally according clinician's plan? *If **no**, please select one relevant reason:*	**Yes** ☐ **No** ☐
Concerned about worsening of seizures	☐
Forgotten to change dose	☐
Instructions not clear	☐

POSTNATAL FOLLOW-UP BOOKLET	Adherence checklist Part 2	Participant UTIN	Visit date
		__/___	DD / MMM / YYYY

AED LEVELS

Has the AED level been checked postnatally by anyone outside the EMPIRE Trial team? *If yes, please specify below:*						Yes ☐ No ☐	
A & E	☐	Obstetrician	☐	Neurologist	☐	Midwife	☐
Has the result been revealed to the local research team?						Yes ☐ No ☐	

Date of Blood Test	AED Medication	Test result for serum level		
		Value	Unit	
DD / MMM / YY			µmol/l ☐	mg/l ☐
DD / MMM / YY			µmol/l ☐	mg/l ☐
DD / MMM / YY			µmol/l ☐	mg/l ☐
DD / MMM / YY			µmol/l ☐	mg/l ☐
DD / MMM / YY			µmol/l ☐	mg/l ☐
If yes, please report the unblinding to Trial Coordinator				

ANY ADDITIONAL MEDICATION

Medication	Total daily dose (mg)	Start date	Ongoing?	End date
Diazepam or clobazam		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY

POSTNATAL FOLLOW-UP BOOKLET	Adherence checklist Part 3	Participant UTIN	Visit date
		__ __/__ __ __	DD / MMM / YYYY

HOSPITAL ADMISSION

Has the patient been admitted to hospital since delivery?							Yes ☐ No ☐	Was it epilepsy related?
Admission 1	Date & Time of admission	DD / MMM / YY	HH : MM	Date & Time of discharge	DD / MMM / YY	HH : MM		Yes ☐ No ☐
Admission 2	Date & Time of admission	DD / MMM / YY	HH : MM	Date & Time of discharge	DD / MMM / YY	HH : MM		Yes ☐ No ☐
Admission 3	Date & Time of admission	DD / MMM / YY	HH : MM	Date & Time of discharge	DD / MMM / YY	HH : MM		Yes ☐ No ☐
Admission 4	Date & Time of admission	DD / MMM / YY	HH : MM	Date & Time of discharge	DD / MMM / YY	HH : MM		Yes ☐ No ☐

TOXICITY

Did AED toxicity occur at any point during 6 weeks post delivery?	Yes ☐ No ☐
Did any of the following symptoms occur?	
dizziness	Yes ☐ No ☐
unsteadiness	Yes ☐ No ☐
nausea	Yes ☐ No ☐
headache	Yes ☐ No ☐
vomiting	Yes ☐ No ☐
Did toxicity result in medical intervention?	
Yes ☐ No ☐ *If* ***yes****, please specify:*	
☐ Admission to ward	☐ Change in medication
☐ Out-patient or GP appointment	☐ Seen and discharged at A&E
☐ Admission to ICU	☐ Telephone advice
☐ Other *(if yes, please specify)*	