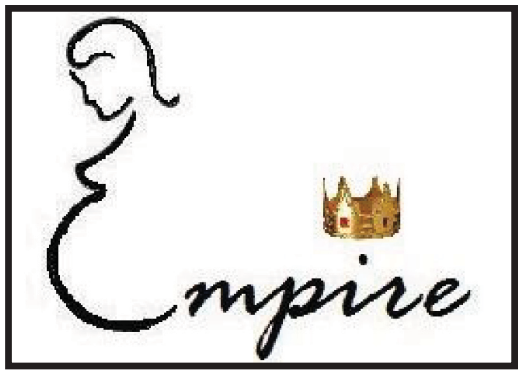

ANTENATAL FOLLOW-UP BOOKLET

Patient UTIN: __ __/__ __ __

ANTENATAL FOLLOW-UP BOOKLET	Visit checklist Part 1	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

Gestational age	_____weeks _____days

CHECKLIST		ACTION
Have you received a PURPLE ALERT or requested any non trial serum AED levels?	**Yes** ☐	Check that serum AED levels collected since the participant's entry into the trial have been received from the trial office and have been recorded in **Purple Alert Form (PAF)**.
	No ☐	No action required
Has a blood sample been taken?	**Yes** ☐	Centrifuge and package sample according to SOP no.3 Blood collection and processing Send EMPIRE trial blood request form to trial office
	No ☐	Please take blood sample and package 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 participant completed <u>all</u> relevant pages of the EMPIRE diary	**Yes** ☐	Please file diary in participant's CRF file and provide participant with a new diary Please enter next clinic visit date and time in participants diary.
	No ☐	Please ask participant to recall as much information since the last visit as possible and document in diary.
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:***

FOR PARTICIPANTS BETWEEN 32 - 36 WEEKS GESTATION ONLY **Has the participant completed:** **QOLIE 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:***

ANTENATAL FOLLOW-UP BOOKLET	Visit checklist Part 2	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

CHECKLIST		ACTION
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
FOR PARTICIPANTS 20 WEEKS GESTATION ONLY **Has a routine ultrasound been conducted?**	**Yes** ☐	Please complete **Ultrasound form for congenital abnormalities in midtrimester** and file in participant's CRF file.
	No ☐	No further action.
FOR PARTICIPANTS 24 WEEKS & OVER ONLY **Is an ultrasound scan for fetal growth required?**	**Yes** ☐	Please complete **Ultrasound form for fetal growth** and file in participant's CRF file
	No ☐	No further action

ANTENATAL FOLLOW-UP BOOKLET	AED Medication Part 1	Participant UTIN	Visit date
		__ __/__ __ __	__ /MMM /YYYY

CURRENT TREATMENT

Current AED. Please use Brand name, if prescribed	Current daily dose (mg)	Does the dose need to be changed today?	New daily dose (mg)
carbamazepine (generic) **Yes** ☐ **No** ☐			
Tegretol (brand) **Yes** ☐ **No** ☐		**Yes** ☐ **No** ☐	
Tegretol Retard (brand) **Yes** ☐ **No** ☐			
lamotrigine (generic) **Yes** ☐ **No** ☐		**Yes** ☐	
Lamictal (brand) **Yes** ☐ **No** ☐		**No** ☐	
levetiracetam (generic) **Yes** ☐ **No** ☐		**Yes** ☐	
Keppra (brand) **Yes** ☐ **No** ☐		**No** ☐	
phenytoin (generic) **Yes** ☐ **No** ☐		**Yes** ☐	
Epanutin (brand) **Yes** ☐ **No** ☐		**No** ☐	
sodium valproate (generic) **Yes** ☐ **No** ☐		**Yes** ☐	
Epilim (brand) **Yes** ☐ **No** ☐		**No** ☐	

Have you adding any new AED medication today? *If **yes**, please update specify drug name (brand) and dose below*	**Yes** ☐ **No** ☐

Drug name:	**Daily dose (mg):**

If dose is being changed or a new drug added today, was this in response to? *(please tick one)*

Purple alert ☐ Clinical concerns ☐ Patient concerns ☐

Has there been any change in the treatment between the last clinic visit and patient's visit today?

Yes ☐ **No** ☐ *If **yes**, please update* ***'TREATMENT MODIFICATION'*** **in next section'**

Since the last visit, has the team received a PURPLE ALERT for this patient?

Yes ☐ **No** ☐ *If **yes**, please fill the **PURPLE ALERT** section in the end of this booklet*

ANTENATAL FOLLOW-UP BOOKLET	AED Medication Part 2	Participant UTIN	Visit date
		_ _/_ _ _	DD / MMM / YYYY

TREATMENT MODIFICATION SINCE LAST CLINICAL VISIT

CAUTION! Please record **all** changes in treatment in separate rows, alike if the change refers to dosage change, change of a drug's brand, drug discontinuation or commencement.

New drug or dosage change of already received one?	AED name	Daily dose before change* (mg)	Date of change, drug introduction or discontinuation	Daily dose after change or start dose in case of new drug (mg)	If dose changed since last visit, who made the change?	If dose changed since last visit, was this in response to? *(please tick one)?*
New drug ☐ Dose change ☐ Drug stopped ☐			DD / MMM / YYYY		Clinical team ☐ Patient ☐	Purple alert ☐ Clinical concerns ☐ Patient concerns ☐
New drug ☐ Dose change ☐ Drug stopped ☐			DD / MMM / YYYY		Clinical team ☐ Patient ☐	Purple alert ☐ Clinical concerns ☐ Patient concerns ☐
New drug ☐ Dose change ☐ Drug stopped ☐			DD / MMM / YYYY		Clinical team ☐ Patient ☐	Purple alert ☐ Clinical concerns ☐ Patient concerns ☐
New drug ☐ Dose change ☐ Drug stopped ☐			DD / MMM / YYYY		Clinical team ☐ Patient ☐	Purple alert ☐ Clinical concerns ☐ Patient concerns ☐

New drug or dosage change of already received one?	AED name	Daily dose before change* (mg)	Date of change, drug introduction or discontinuation	Daily dose after change or start dose in case of new drug (mg)	If dose changed since last visit, who made the change?	If dose changed since last visit, was this in response to? *(please tick one)?*
New drug ☐ Dose change ☐ Drug stopped ☐			DD / MMM / YYYY		Clinical team ☐ Patient ☐	Purple alert ☐ Clinical concerns ☐ Patient concerns ☐

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

TREATMENT ADHERENCE

Has the patient taken the Trial AED(s) according to the clinician's plan?	**Yes** ☐ **No** ☐ *If **no**, please select **one** relevant reason:*
Concerned about effects to baby	☐
Concerned about side effects	☐
Forgotten to change dose	☐
Instructions not clear	☐
Has the AED serum level been checked by anyone outside the trial protocol?	**Yes** ☐ **No** ☐

If yes please specify by whom and record serum level(s) below:

A & E	☐	Obstetrician	☐	Neurologist	☐	Midwife	☐

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

HOSPITAL ADMISSION

Has the patient been admitted to hospital since her last visit?					**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** ☐
Admission 5	**Date & Time of admission**	DD /MMM /YY	HH :MM	**Date & Time of discharge**	DD /MMM /YY	HH :MM	**Yes** ☐ **No** ☐

ANTENATAL FOLLOW-UP BOOKLET	Non-AE medication	Participant UTIN	Visit date
		_ _/_ _ _	DD / MMM / YYYY

ADDITIONAL MEDICATION

This part is to be used to document all dose changes for **all** **non-AE medication** taken from the start of the trial up until the visit.

Medication	Total daily dose (mg)	Start date	Ongoing?	End date
Folic Acid		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
Vitamin K		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
Methyldopa		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
Nifedipine		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
Insulin		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
Metformin		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
Labetelol		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
Ferrous sulphate		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
Aspirin		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
Diazepam or clobazam		DD / MMM / YYYY	Yes ☐ No ☐	DD / MMM / YYYY
If any OTHER non-AED medication (other than listed above) is being used, please specify medication's name and fill in following gaps:				
		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

ANTENATAL FOLLOW-UP BOOKLET	Ultrasound form for congenital abnormalities in midtrimester	Participant UTIN	Date
		_ _/_ _ _	DD /MMM /YYYY

Was an ultrasound performed?		**Yes** ☐ **No** ☐ *If **yes**, please complete the following:*	
Is the pregnancy multiple?	**Yes** ☐ **No** ☐	*If **yes**, please specify* ☐ **Twins** ☐ **Triplets** ☐ **More**	
Fetus (no.)		**Gestational Age**	_____weeks _____days
Congenital malformations	**Yes** ☐ **No** ☐ *If **yes**, please specify below*		
Spina bifida	**Yes** ☐ **No** ☐	**Hydrocephalus**	**Yes** ☐ **No** ☐
Diaphragmatic hernia	**Yes** ☐ **No** ☐	**Anencephaly**	**Yes** ☐ **No** ☐
Cleft lip	**Yes** ☐ **No** ☐	**Congenital heart disease**	**Yes** ☐ **No** ☐
Cleft palate	**Yes** ☐ **No** ☐	**Tumours**	**Yes** ☐ **No** ☐
Gastroschisis	**Yes** ☐ **No** ☐	**Limb abnormalities**	**Yes** ☐ **No** ☐
Duodenal atresia	**Yes** ☐ **No** ☐	**External genital abnormalities**	**Yes** ☐ **No** ☐
Congenital Cystic Adenomatoid Malformation	**Yes** ☐ **No** ☐	**Other, please specify:**	**Yes** ☐ **No** ☐
Was a fetal echo performed?		**Yes** ☐ **No** ☐ **Not done** ☐	
*If **yes**,* please specify if fetal echo was: Normal ☐ Abnormal ☐		**<u>If abnormal,</u> please specify abnormality:**	
Fetus (no.)		**Gestational Age**	_____weeks _____days
Congenital malformations	**Yes** ☐ **No** ☐ *If **yes**, please specify below*		
Spina bifida	**Yes** ☐ **No** ☐	**Hydrocephalus**	**Yes** ☐ **No** ☐
Diaphragmatic hernia	**Yes** ☐ **No** ☐	**Anencephaly**	**Yes** ☐ **No** ☐
Cleft lip	**Yes** ☐ **No** ☐	**Congenital heart disease**	**Yes** ☐ **No** ☐
Cleft palate	**Yes** ☐ **No** ☐	**Tumours**	**Yes** ☐ **No** ☐
Gastroschisis	**Yes** ☐ **No** ☐	**Limb abnormalities**	**Yes** ☐ **No** ☐
Duodenal atresia	**Yes** ☐ **No** ☐	**External genital abnormalities**	**Yes** ☐ **No** ☐
Congenital Cystic Adenomatoid Malformation	**Yes** ☐ **No** ☐	**Other, please specify:**	**Yes** ☐ **No** ☐
Was a fetal echo performed?		**Yes** ☐ **No** ☐ **Not done** ☐	
*If **yes**,* please specify if fetal echo was: Normal ☐ Abnormal ☐		**<u>If abnormal,</u> please specify abnormality:**	

ANTENATAL FOLLOW-UP BOOKLET	Ultrasound form for fetal growth	Participant UTIN	Date
		_ _/_ _ _	DD /MMM /YYYY

Was fetal growth measured?	**Yes** ☐ **No** ☐ *If **yes**, please complete the following*			
Date of scan	DD /MMM /YYYY			
Is the pregnancy multiple?	**Yes** ☐ **No** ☐	*If **yes**, please specify* ☐ **Twins** ☐ **Triplets** ☐ **More**		
Fetus number		**Gestational Age**	_____weeks _____days	
Small for Gestational Age *(defined as birth weight less than 10th centile)*	**Yes** ☐ **No** ☐	**Customised centile used**	**Yes** ☐ **No** ☐	
Umbilical artery Doppler	Normal		☐	
	Absent end diastolic flow (EDF)		☐	
	Reversed end diastolic flow (EDF)		☐	
	Raised pulsatility index		☐	
Liquor volume	Normal		☐	
	Reduced		☐	
	Excess		☐	
Fetus number		**Gestational Age**	_____weeks _____days	
Small for Gestational Age *(defined as birth weight less than 10th centile)*	**Yes** ☐ **No** ☐	**Customised centile used**	**Yes** ☐ **No** ☐	
Umbilical artery Doppler	Normal		☐	
	Absent end diastolic flow (EDF)		☐	
	Reversed end diastolic flow (EDF)		☐	
	Raised pulsatility index		☐	
Liquor volume	Normal		☐	
	Reduced		☐	
	Excess		☐	

ANTENATAL FOLLOW-UP BOOKLET	Purple alert record	Participant UTIN	Date
		__ __/__ __ __	__ /____ /____

Please, fill this section only if you received a PURPLE ALERT for this patient since the last clinical visit.

If you received PURPLE ALERT for this patient, did you inform the patient about it?	**Yes** ☐ **No** ☐
*If you **did not** inform the patient, please give reason below:*	
What action was taken as a result of the PURPLE alert?	
a. Offer to patient to increase AED dose	**Yes** ☐ **No** ☐
*If **yes**, did patient accept increase in dose?*	**Yes** ☐ **No** ☐
*If you **did not** offer an increase in dose, please give reason below:*	
b. Follow-up visit brought forward	**Yes** ☐ **No** ☐
c. Other action taken	**Yes** ☐ **No** ☐
*If **yes**, please specify:*	