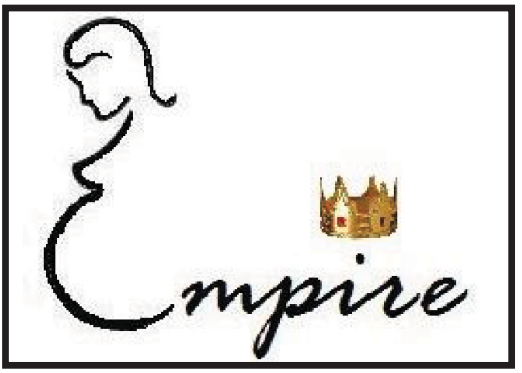

BASELINE BOOKLET

Patient UTIN: __ __/__ __ __

BASELINE BOOKLET	Visit checklist 1	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

CHECKLIST (Completed Y/N)		ACTION
Have you advised the trial office that the participant has been recruited to EMPIRE by faxing Recruitment form: Parts 1 & 2?	**Yes** ☐	File completed **Recruitment Form: parts 1 & 2**
	No ☐	Send **Recruitment Form: parts 1 & 2** AND EMPIRE Trial blood request form to the trial office. Proceed according to SOP no. 3 Blood collection and processing
Has a blood sample been taken?	**Yes** ☐	Centrifuge and package sample according to SOP no. 3 Blood collection and processing
	No ☐	Please take blood sample and package according to SOP no. 3 Blood collection and processing Or Document reason why blood sample was not taken ***Please state here:***
Have you provided the participant with the EMPIRE diary?	**Yes** ☐	Explain how diary is to be completed.
	No ☐	Please provide participant with diary and explain how it is to be completed. Or Document reason why diary not given ***Please state here:***
Have you completed Baseline Booklet?	**Yes** ☐	File **Baseline Booklet** in participant's CRF file.
	No ☐	Complete **Baseline Booklet** and file in participant's CRF file.
Has the participant completed: **Patient's questionnaire (EQ-5d, LAEP& cost 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:***

To be continued on the next page

BASELINE BOOKLET	Visit checklist 2	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

CHECKLIST (Completed Y/N)		ACTION
Has the participant completed: **QOLIE 31 questionnaire?**	**Yes** ☐	Return completed **QOLIE 31 questionnaire** to participant's CRF file.
	No ☐	Ask participant to complete **QOLIE 31 questionnaire** and file in participant's CRF file. OR Document reason why not completed. ***Please state here:***
Has the participant completed: **NDDI-E screening tool?**	**Yes** ☐	Return completed **NDDI-E** to participant's CRF file. Score above 15 may imply existence of depression. If the case, please refer accordingly to your usual clinical practice.
	No ☐	Ask participant to complete **NDDI-E screening tool** and file in participant's CRF file. **OR** Document reason why not completed. ***Please state here:***
Have you completed Purple Alert and Adverse Events Forms?	**Yes** ☐	File is in participant's CRF file.
	No ☐	Complete if necessary and file in participant's CRF file.

BASELINE BOOKLET	Recruitment form Part 1	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

IMPORTANT: Part 1 & 2 of this form MUST be completed and sent to the Trial Co-ordinator along with the EMPIRE blood request form on the day of the participant's recruitment

Please, state the date when the patient consent was obtained	DD /MMM /YYYY

PRE-TRIAL SERUM AED LEVEL (PRE-PREGNANCY OR EARLY PREGNANCY)

As the treating clinician you have the choice of setting a pre-pregnancy serum AED level (PPSL) OR the Early Pregnancy serum AED level (taken in pregnancy prior to trial baseline visit) (EPSL) as the 'target' level. If a pre-pregnancy level is to be used it should be taken within the last 12 months. You should be confident that when this level was taken the participant was adherent to treatment, on the same current daily dosage and ideally the time interval between the oral dosage and serum level will be similar to those taken throughout the pregnancy.

PRE-PREGNANCY SERUM AED LEVEL (PPSL)	
As the treating clinician are you confident that:	
The participant's serum level has been taken pre-pregnancy and recorded in the last 12 months?	**Yes** ☐ **No** ☐
You know the timing of the serum level and the last dose taken?	**Yes** ☐ **No** ☐
Do you think the serum level of AED in pre-pregnancy takes into account the time of the day of intake?	**Yes** ☐ **No** ☐
If you have answered yes to all the above are you happy for the pre-pregnancy serum AED level to be the target level for the trial?	**Yes** ☐ **No** ☐
If yes, please set pre-pregnancy serum AED level as the target AED level for the trial.	
EARLY PREGNANCY SERUM AED LEVEL (EPSL) (TAKEN IN PREGNANCY PRIOR TO TRIAL BASELINE VISIT)	
As the treating clinician are you confident that:	
The participant's serum level has been taken in this pregnancy?	**Yes** ☐ **No** ☐
You know the timing of the serum level and the last dose taken?	**Yes** ☐ **No** ☐
Do you think the serum level of AED in this pregnancy takes into account the time of the day of intake?	**Yes** ☐ **No** ☐
If you have answered yes to all the above are you happy for the pre-trial serum AED level to be the target level for the trial?	**Yes** ☐ **No** ☐
If yes, please set pregnancy serum AED level as the target AED level for the trial. **Do that *ONLY* if pre-pregnancy level is not set as a target.**	

BASELINE BOOKLET	Recruitment form Part 2	Participant UTIN	Visit date
		__ __/__ __ __	__ /MMM /YYYY

Please present all available data regarding pre-trial AED serum levels i.e. pre-pregnancy AED serum levels (PPSL), early pregnancy serum levels (EPSL) or both.

Current AED Please use Brand name, if prescribed	Total daily dose (mg)	AED serum level known	SERUM LEVEL Value	 Unit	Date AED level taken	Use as the EMPIRE serum target level	
carbamazepine (generic) Yes ☐ No ☐		PPSL ☐		µmol/l ☐ mg/l ☐	DD /MMM /YYYY	Yes No	☐ ☐
Tegretol (brand) Yes ☐ No ☐		EPSL ☐		µmol/l ☐ mg/l ☐	DD /MMM /YYYY	Yes No	☐ ☐
Tegretol Retard (brand) Yes ☐ No ☐		Neither ☐					
lamotrigine (generic) Yes ☐ No ☐		PPSL ☐		µmol/l ☐ mg/l ☐	DD /MMM /YYYY	Yes No	☐ ☐
		EPSL ☐		µmol/l ☐ mg/l ☐	DD /MMM /YYYY	Yes No	☐ ☐
Lamictal (brand) Yes ☐ No ☐		Neither ☐					
levetiracetam (generic) Yes ☐ No ☐		PPSL ☐		µmol/l ☐ mg/l ☐	DD /MMM /YYYY	Yes No	☐ ☐
		EPSL ☐		µmol/l ☐ mg/l ☐	DD /MMM /YYYY	Yes No	☐ ☐
Keppra (brand) Yes ☐ No ☐		Neither ☐					
phenytoin (generic) Yes ☐ No ☐		PPSL ☐		µmol/l ☐ mg/l ☐	DD /MMM /YYYY	Yes No	☐ ☐
		EPSL ☐		µmol/l ☐ mg/l ☐	DD /MMM /YYYY	Yes No	☐ ☐
Epanutin (brand) Yes ☐ No ☐		Neither ☐					

Gestational age	_____weeks _____days
Did the participant experience seizures (any type) during the 3 months prior to her pregnancy?	**Yes** ☐ **No** ☐

BASELINE BOOKLET	Baseline form AED Medication	Participant UTIN	Visit date
		__ __/__ __ __	DD / MMM / YYYY

AED MEDICATION

This part is to be used to document all dose changes for **all** **AED medication** taken 6 months prior to the start of the trial up until this visit.

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

BASELINE BOOKLET	Baseline form Non-AED Medication	Participant UTIN	Visit date
		__ __/__ __ __	DD / MMM / YYYY

NON-AED MEDICATION

This part is to be used to document all dose changes for **all** **non AED medication** taken 6 months prior to the start of the trial up until the final post natal 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
If any other medication is being used, please specify medication name and fill in following gaps. ***If not applicable please cross the section.***				
		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

BASELINE BOOKLET	Baseline Form Surgical & Obstetric History	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

SURGICAL HISTORY

Has the participant had any intracranial surgery prior to the study visit?	**Yes** ☐ **No** ☐
If yes, please specify	
Date	DD /MMM /YYYY

VAGAL NERVE STIMULATION (VNS)

Does the patient have a VNS device fitted?	**Yes** ☐ **No** ☐	**If yes, current status of the VNS device**	**On** ☐ **Off** ☐

GRAVIDA & PARITY

Gravida (Number of pregnancies including this one)		**Parity** (Number of previous births at 24 weeks or more gestation)	

PREVIOUS PREGNANCY COMPLICATIONS

Has the participant had any terminations or miscarriages? *If yes, please specify below:*			**Yes** ☐ **No** ☐
Total number of terminations			
Total number of miscarriages			
Number of 1st trimester miscarriages		**Number of 2nd trimester miscarriages**	

Previous maternal history					
Pre-eclampsia	**Yes** ☐ **No** ☐	Eclampsia	**Yes** ☐ **No** ☐	Gestational diabetes	**Yes** ☐ **No** ☐
Antepartum haemorrhage	**Yes** ☐ **No** ☐	Abruption	**Yes** ☐ **No** ☐	Caesarean section	**Yes** ☐ **No** ☐
Postpartum haemorrhage	**Yes** ☐ **No** ☐	Infection	**Yes** ☐ **No** ☐	Other	**Yes** ☐ **No** ☐
***If Other**, please specify*					
Admission to hospital due to seizures in previous pregnancies				**Yes** ☐ **No** ☐	

BASELINE BOOKLET	Baseline Form Medical History (excluding epilepsy)	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

MEDICAL HISTORY

Is there a history of:		Patient	Family history
1. Congenital abnormalities		Yes ☐ No ☐	Yes ☐ No ☐
2. Learning difficulties		Yes ☐ No ☐	Yes ☐ No ☐
3. Diabetes		Yes ☐ No ☐	Yes ☐ No ☐
4. Chronic Hypertension		Yes ☐ No ☐	Yes ☐ No ☐
5. Renal disease		Yes ☐ No ☐	Yes ☐ No ☐
6. Immunological problems		Yes ☐ No ☐	Yes ☐ No ☐
If yes, please specify:	a) Systemic Lupus	Yes ☐ No ☐	Yes ☐ No ☐
	b) Erythematosis	Yes ☐ No ☐	Yes ☐ No ☐
	c) Rheumatoid arthritis	Yes ☐ No ☐	Yes ☐ No ☐
	d) If other, please specify here		
7. Cardiac disease		Yes ☐ No ☐	Yes ☐ No ☐
	If yes, please specify here		
8. Haematological disorders		Yes ☐ No ☐	Yes ☐ No ☐
If yes, please specify:	a) Deep vein thrombosis	Yes ☐ No ☐	Yes ☐ No ☐
	b) Pulmonary embolism	Yes ☐ No ☐	Yes ☐ No ☐
	c) Thrombocytopenia	Yes ☐ No ☐	Yes ☐ No ☐
	d) If other, please specify here		
9. HIV		Yes ☐ No ☐	Yes ☐ No ☐
10. Tuberculosis		Yes ☐ No ☐	Yes ☐ No ☐

11. Any genetically inherited disorders *If yes, please specify here*		**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
12. Mental illness		**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
If yes, please specify:	a) Majo r depression	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
	b) Puerperal psychosis	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
	c) Bipolar disorder	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
	d) Schizophrenia	**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐
	e) If other, please specify here		
13. Any other *If yes, please specify here*		**Yes** ☐ **No** ☐	**Yes** ☐ **No** ☐

BASELINE BOOKLET	Baseline Form Epilepsy History	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

DIAGNOSIS OF EPILEPSY

Age at first seizure (excluding febrile)	years	Date of first seizure (excluding febrile)	DD /MMM /YYYY

AETIOLOGY OF EPILEPSY

Idiopathic, assumed genetic	☐		
Structural *(if yes, please specify)*	☐	**Trauma** ☐ **Space occupying lesions** ☐ **Vascular malformation** ☐	**Stroke** ☐ **SLE** ☐ **Other** *(if yes please specify below)* ☐
Cryptogenic	☐		
Infection *(if yes, please specify)*	☐	**Encephalitis** ☐	**HIV** ☐
Metabolic *(if yes, please specify)*	☐	**Alcohol** ☐	**Drug** ☐

EPILEPSY SYNDROME

Syndrome		Please tick one
Partial Epilepsy	Symptomatic or cryptogenic partial epilepsy	☐
	Temporal lobe	☐
	Frontal lobe	☐
	Parietal lobe	☐
	Occipital lobe	☐
	Localisation unknown	☐
Generalised	Juvenile myoclonic epilepsy	☐
	Tonic clonic seizures on wakening	☐
	Childhood absence epilepsy	☐
	Juvenile absence epilepsy	☐
Unclassified Epilepsy/Other syndromic diagnosis		☐

BASELINE BOOKLET	Baseline Form Seizure types	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

SEIZURE CLASSIFICATION & FREQUENCY

Seizure description (s) Has the participant ever experienced any of the following:		Yes/No	Number of seizures in the 3 months prior to pregnancy (if exact number not known, please give best estimate)	Number of seizures since becoming pregnant (if exact number not known, please give best estimate)
Generalized	Tonic clonic *(including secondary generalized seizures)*	**Yes** ☐ **No** ☐		
	Absence	**Yes** ☐ **No** ☐		
	Myoclonus	**Yes** ☐ **No** ☐		
Partial	Simple	**Yes** ☐ **No** ☐		
	Complex	**Yes** ☐ **No** ☐		
Unclassified/Other		**Yes** ☐ **No** ☐		

CLUSTERS

Has the patient had a seizure cluster?	**Yes** ☐ **No** ☐	Date of last seizure cluster	DD /MMM /YYYY

BASELINE BOOKLET	Baseline Form EEG/MRI	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

EEG INTERPRETATION (IF AVAILABLE)

Has an EEG been performed at any time?	**Yes** ☐ **No** ☐	**Date**	DD /MMM /YYYY
Result known *If **yes,** please specify outcome below:*	**Yes** ☐ **No** ☐		
Is EEG normal?	**Yes** ☐ **No** ☐		
If abnormal, is it clinically significant?	**Yes** ☐ **No** ☐		
If clinically significant please specify	**Focal epileptiform discharges** ☐	*If **yes**, please specify:*	
	Generalised epileptiform discharges ☐	*If **yes**, please specify:*	
	Other ☐	*If **yes**, please specify:*	

MRI/CT INTERPRETATION (IF AVAILABLE)

Has an MRI been performed at any time?	**Yes** ☐ **No** ☐	**Date**	DD / MMM / YYYY
Result known	**Yes** ☐ **No** ☐	*If **yes,** please specify outcome:*	
Has the MRI demonstrated aetiology of epilepsy? *If yes, please specify below*	**Yes** ☐ **No** ☐		
Tumour	**Yes** ☐ **No** ☐	**Vascular malformation**	**Yes** ☐ **No** ☐
Previous trauma	**Yes** ☐ **No** ☐	**Hippocampal sclerosis**	**Yes** ☐ **No** ☐
Previous stroke	**Yes** ☐ **No** ☐	**Cortical dysplasia**	**Yes** ☐ **No** ☐
Other *(if yes please specify)*	**Yes** ☐ **No** ☐		
Has a CT been performed?	**Yes** ☐ **No** ☐	**Date**	DD / MMM / YYYY
Result known	**Yes** ☐ **No** ☐	*If **yes,** please specify outcome:*	
Has the CT demonstrated aetiology of epilepsy? *If yes, please specify:*	**Yes** ☐ **No** ☐		
Tumour	**Yes** ☐ **No** ☐	**Previous stroke**	**Yes** ☐ **No** ☐
Previous trauma	**Yes** ☐ **No** ☐	**Vascular malformation**	**Yes** ☐ **No** ☐
Other, *if yes please specify*	**Yes** ☐ **No** ☐		

BASELINE BOOKLET	Baseline Form Demographics Part 1	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

DEMOGRAPHICS

MOTHER'S ETHNIC GROUP

Please tick only one

White		**Black or Black British**	
British	☐	African	☐
Irish	☐	Caribbean	☐
White other	☐	Black other	☐

Asian or Asian British		**Mixed**		**Other ethnic group**	
Bangladeshi	☐	Mixed – White/Black African	☐	Other ethnic group	☐
Indian	☐	Mixed – White/Black Caribbean	☐		
Pakistani	☐	Mixed – White/Asian	☐	Not given	☐
Chinese	☐	Mixed – White/Chinese	☐		
Asian other	☐	Mixed other	☐		

HEIGHT AND WEIGHT

Height	cm	**Weight**	kg

PATIENT'S AGE

Years		**Months**	

BASELINE BOOKLET	Baseline Form Demographics Part 2	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

EMPLOYMENT & DRIVING STATUS

Employed – Full-time ☐		**Holds a valid driving licence**	**Yes** ☐ **No** ☐
Employed – Part-time ☐			
Self – employed ☐		**Medically fit to drive**	**Yes** ☐ **No** ☐
Unemployed ☐			

EDUCATIONAL DETAILS

Highest qualification	Degree Level ☐
	A Level ☐
	GCSE Level ☐
	Below GCSE Level ☐
School leaving age	_____ yrs

NICOTINE & ALCOHOL CONSUMPTION DURING PREGNANCY

Smoker	☐	***If yes, specify*** **number of cigarettes per day**		
Ex-smoker	☐	***If yes, specify*** **how long ago patient stopped smoking**	0 – 3 months ☐	3+ months ☐
Non-smoker	☐			

Average number of alcohol units <u>per week</u>	

Examples

Units	Example
1 unit	Half pint of ordinary strength beer, lager, or cider (3-4% alcohol by volume) or a small pub measure (25 ml) of spirits (40% alcohol by volume)
2 units	Medium glass of 12.5% wine (175ml) or can of 4.5% beer (440ml)
3 units	Large glass of 12.5% wine (250ml) or pint of 6% cider

BASELINE BOOKLET	Baseline Form Previous children	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

CHILDREN

Please use the following sheets to document information about all of the participant's previous births/children. Please begin with the most recent birth/child. One sheet should be used per child.
If not applicable, please cross all irrelevant sections.

Child number		**Gender**	**Male** ☐ **Female** ☐	**DOB**	DD /MMM /YYYY
Gestational age at delivery		**wks**		**Birth weight**	**kg**
Neonatal death		**Yes** ☐ **No** ☐		**Still birth**	**Yes** ☐ **No** ☐
Delivery mode	**Spontaneous Vaginal** ☐	**Forceps** ☐	**Ventouse** ☐	**Caesarean section** ☐	
AED Exposure *If **yes**, please **specify AEDs** taken when pregnant with this child:*			**Yes** ☐ **No** ☐		
lamotrigine	**Yes** ☐ **No** ☐		**levetiracetam**	**Yes** ☐ **No** ☐	
carbamazepine	**Yes** ☐ **No** ☐		**sodium valproate**	**Yes** ☐ **No** ☐	
phenytoin	**Yes** ☐ **No** ☐		**Other,** *if yes please specify*	**Yes** ☐ **No** ☐	
Congenital malformations *(if **yes**, please specify below)*			**Yes** ☐ **No** ☐		
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,** *if yes please specify*	**Yes** ☐ **No** ☐	
Epilepsy in childhood				**Yes** ☐ **No** ☐	
Regular follow-up for neuro-developmental concerns				**Yes** ☐ **No** ☐	
Statement of special educational needs?				**Yes** ☐ **No** ☐	
ADHD Attention deficit hyperactivity disorder	**Yes** ☐ **No** ☐	**Aspergers syndrome**	**Yes** ☐ **No** ☐	**Autism**	**Yes** ☐ **No** ☐

BASELINE BOOKLET	Baseline Form Previous children	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

CHILDREN

Please use the following sheets to document information about all of the participant's previous births/children. Please begin with the most recent birth/child. One sheet should be used per child.
If not applicable, please cross all irrelevant sections.

Child number		**Gender**	**Male** ☐ **Female** ☐	**DOB**	DD /MMM /YYYY
Gestational age at delivery		**wks**	**Birth weight**		**kg**
Neonatal death *(below 28 days)*		**Yes** ☐ **No** ☐	**Still birth**		**Yes** ☐ **No** ☐
Delivery mode	**Spontaneous Vaginal** ☐	**Forceps** ☐	**Ventouse** ☐	**Caesarean section** ☐	

AED Exposure *If **yes,** please **specify AEDs** taken when pregnant with this child:*		**Yes** ☐ **No** ☐	
lamotrigine	**Yes** ☐ **No** ☐	**levetiracetam**	**Yes** ☐ **No** ☐
carbamazepine	**Yes** ☐ **No** ☐	**sodium valproate**	**Yes** ☐ **No** ☐
phenytoin	**Yes** ☐ **No** ☐	**Other,** *if yes please specify*	**Yes** ☐ **No** ☐
Congenital malformations *(if **yes**, please specify below)*		**Yes** ☐ **No** ☐	
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,** *if yes please specify*	**Yes** ☐ **No** ☐
Epilepsy in childhood			**Yes** ☐ **No** ☐
Regular follow-up for neuro-developmental concerns			**Yes** ☐ **No** ☐
Statement of special educational needs?			**Yes** ☐ **No** ☐

ADHD **Attention deficit hyperactivity disorder**	**Yes** ☐ **No** ☐	**Aspergers syndrome**	**Yes** ☐ **No** ☐	**Autism**	**Yes** ☐ **No** ☐

BASELINE BOOKLET	Baseline Form Previous children	Participant UTIN	Visit date
		_ _/_ _ _	DD /MMM /YYYY

CHILDREN

Please use the following sheets to document information about all of the participant's previous births/children. Please begin with the most recent birth/child. One sheet should be used per child.
If not applicable, please cross all irrelevant sections.

Child number		**Gender**	**Male** ☐ **Female** ☐	**DOB**	DD /MMM /YYYY
Gestational age at delivery		**wks**		**Birth weight**	**kg**
Neonatal death *(below 28 days)*		**Yes** ☐ **No** ☐		**Still birth**	**Yes** ☐ **No** ☐
Delivery mode	**Spontaneous Vaginal** ☐	**Forceps** ☐	**Ventouse** ☐	**Caesarean section** ☐	
AED Exposure *If **yes**, please **specify AEDs** taken when pregnant with this child:*			**Yes** ☐ **No** ☐		
lamotrigine	**Yes** ☐ **No** ☐		**levetiracetam**	**Yes** ☐ **No** ☐	
carbamazepine	**Yes** ☐ **No** ☐		**sodium valproate**	**Yes** ☐ **No** ☐	
phenytoin	**Yes** ☐ **No** ☐		**Other,** *if yes please specify*	**Yes** ☐ **No** ☐	
Congenital malformations *(if **yes**, please specify below)*			**Yes** ☐ **No** ☐		
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,** *if yes please specify*	**Yes** ☐ **No** ☐	
Epilepsy in childhood				**Yes** ☐ **No** ☐	
Regular follow-up for neuro-developmental concerns				**Yes** ☐ **No** ☐	
Statement of special educational needs?				**Yes** ☐ **No** ☐	
ADHD **Attention deficit hyperactivity disorder**	**Yes** ☐ **No** ☐	**Aspergers syndrome**	**Yes** ☐ **No** ☐	**Autism**	**Yes** ☐ **No** ☐

BASELINE BOOKLET	Baseline Form Previous children	Participant UTIN	Visit date
		__ __/__ __ __	DD /MMM /YYYY

CHILDREN

Please use the following sheets to document information about all of the participant's previous births/children. Please begin with the most recent birth/child. One sheet should be used per child.
If not applicable, please cross all irrelevant sections.

Child number		**Gender**	**Male** ☐ **Female** ☐	**DOB**	DD /MMM /YYYY
Gestational age at delivery		**wks**	**Birth weight**		**kg**
Neonatal death *(below 28 days)*		**Yes** ☐ **No** ☐	**Still birth**		**Yes** ☐ **No** ☐
Delivery mode	**Spontaneous Vaginal** ☐	**Forceps** ☐	**Ventouse** ☐	**Caesarean section** ☐	

AED Exposure *If **yes,** please **specify AEDs** taken when pregnant with this child:*		**Yes** ☐ **No** ☐	
lamotrigine	**Yes** ☐ **No** ☐	**levetiracetam**	**Yes** ☐ **No** ☐
carbamazepine	**Yes** ☐ **No** ☐	**sodium valproate**	**Yes** ☐ **No** ☐
phenytoin	**Yes** ☐ **No** ☐	**Other,** *if yes please specify*	**Yes** ☐ **No** ☐
Congenital malformations *(if **yes**, please specify below)*		**Yes** ☐ **No** ☐	
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,** *if yes please specify*	**Yes** ☐ **No** ☐
Epilepsy in childhood			**Yes** ☐ **No** ☐
Regular follow-up for neuro-developmental concerns			**Yes** ☐ **No** ☐
Statement of special educational needs?			**Yes** ☐ **No** ☐

ADHD **Attention deficit hyperactivity disorder**	**Yes** ☐ **No** ☐	**Aspergers syndrome**	**Yes** ☐ **No** ☐	**Autism**	**Yes** ☐ **No** ☐

BASELINE BOOKLET	Baseline Form Previous children	Participant UTIN	Visit date
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CHILDREN

Please use the following sheets to document information about all of the participant's previous births/children. Please begin with the most recent birth/child. One sheet should be used per child.
If not applicable, please cross all irrelevant sections.

Child number		**Gender**	**Male** ☐ **Female** ☐	**DOB**	DD /MMM /YYYY
Gestational age at delivery		**wks**		**Birth weight**	**kg**
Neonatal death *(below 28 days)*		**Yes** ☐ **No** ☐		**Still birth**	**Yes** ☐ **No** ☐
Delivery mode	**Spontaneous Vaginal** ☐	**Forceps** ☐	**Ventouse** ☐	**Caesarean section** ☐	
AED Exposure *If **yes**, please **specify AEDs** taken when pregnant with this child:*			**Yes** ☐ **No** ☐		
lamotrigine	**Yes** ☐ **No** ☐		**levetiracetam**	**Yes** ☐ **No** ☐	
carbamazepine	**Yes** ☐ **No** ☐		**sodium valproate**	**Yes** ☐ **No** ☐	
phenytoin	**Yes** ☐ **No** ☐		**Other,** *if yes please specify*	**Yes** ☐ **No** ☐	
Congenital malformations *(if **yes**, please specify below)*			**Yes** ☐ **No** ☐		
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,** *if yes please specify*	**Yes** ☐ **No** ☐	
Epilepsy in childhood				**Yes** ☐ **No** ☐	
Regular follow-up for neuro-developmental concerns				**Yes** ☐ **No** ☐	
Statement of special educational needs?				**Yes** ☐ **No** ☐	
ADHD **Attention deficit hyperactivity disorder**	**Yes** ☐ **No** ☐	**Aspergers syndrome**	**Yes** ☐ **No** ☐	**Autism**	**Yes** ☐ **No** ☐