UNIVERSITY OF LEICESTER

Pregnancy Notification Form

PART 1 – Initial Pregnancy Notification

Study Number	Subject ID
EudraCT Number	Study Sponsor
Study Title	

DO NOT SEND IDENTIFIABLE DATA OR SOURCE DOCUMENTS WITH THIS REPORT

1. MATERNAL INFORMATION

Date of Birth ___/___/____

Date of Last Menstrual Period ___/___/____

Expected Date of Delivery ___/___/_____

Method of contraception: _____

Contraception used as instructed?

Yes 1 No 2 Uncertain 3

2. MEDICAL HISTORY (include information on familial disorders, known risk factors or conditions that may affect the outcome of the pregnancy. If none, mark as N/A).

3. PREVIOUS OBSTETRIC HISTORY (provide details on all previous pregnancies, including termination or stillbirth)

	Gestation Week	Outcome Including Any Abnormalities
1	I___I___I	
2	I___I___I	
3	I___I___I	
4	I___I___I	
5	I___I___I	

4. TRIAL MEDICATION INFORMATION (list all trial therapies taken in the 3 months prior to and during pregnancy)

Name of Drug	Daily Dose	Route	Date Started	Date Stopped	Indication	Treatment Start (week of pregnancy)	Treatment Stop (week of pregnancy)

5. NON – TRIAL MEDICATION INFORMATION (list all other (non-trial) medication taken in the 3 months prior to and during pregnancy)

Name of Drug	Daily Dose	Route	Date Started	Date Stopped	Indication	Treatment Start (week of pregnancy)	Treatment Stop (week of pregnancy)

6. PRENATAL INFORMATION

Have any specific tests, e.g. amniocentesis, ultrasound, maternal serum AFP, been performed during the pregnancy so far?

Yes 1 No 2 Not known 3

If Yes, please specify test date and results:

Test _____ Date _____

Result _____

Test _____ Date _____

Result _____

Test _____ Date _____

Result _____

7. MATERNAL PREGNANCY ASSOCIATED EVENTS
If the mother experiences an SAE during the pregnancy, please indicate here, complete an SAE form and submit to the R & D Office immediately.

8. INFORMATION SOURCE

PI details:

Name _____

Address _____

_____

Date of report _____

PI signature _____

ALL REPORTS MUST BE SIGNED AND DATED BY THE PRINCIPAL INVESTIGATOR

PLEASE MAKE A NOTE OF WHEN TO FOLLOW UP THE PREGNANCY OUTCOME

For internal use only
Report received by:
Report received on:
Action taken:

PLEASE FAX THIS REPORT TO THE RESEARCH GOVERNANCE OFFICE ON 0116 258 4226 OR BY EMAIL TO UOLSPONSOR@LEICESTER.AC.UK

Pregnancy Notification Form

PART 2 – Pregnancy Outcome Notification

Study Number	Subject ID
EudraCT Number	Study Sponsor
Study Title	

1. PREGNANCY OUTCOME

a) Termination Yes/No	b) Delivery Yes/No
If yes,	If yes,
Therapeutic/Planned/Spontaneous	Normal/Forceps/Ventouse/Caesarean
Specify the reason and any abnormalities (if known):	Maternal complications or problems related to birth:
Date of Termination:	Date of Delivery:

2. CHILD OUTCOME

Normal/Abnormal/Stillbirth

If any abnormalities, please specify and provide dates:

_____

_____

Sex Male/Female		Apgar Scores (if known)
Length	cm	1 min
Weight	kg	5 mins
Head circumference	cm	10 mins

3. ASSESSMENT OF SERIOUSNESS (OF PREGNANCY OUTCOME)

Non serious
Involved prolonged inpatient hospitalisation
Results in persistent or significant disability/incapacity
Life-threatening
Mother died: Date of death:
Stillbirth/neonate died: Date of death:
Other seriousness criteria
Congenital anomaly/birth defect
Other significant medical event (Please provide details):

4. ASSESSMENT OF CAUSALITY (OF PREGNANCY OUTCOME)
Please indicate the relationship to pregnancy outcome to trial medication:
Unrelated Possibly* Probably* Definitely*

If any of the fields marked* have been ticked, the outcome is considered to be RELATED to the study drug.

5. ADDITIONAL INFORMATION

6. INFORMATION SOURCE

PI details:

Name _____

Address _____

_____

Date of report _____

PI signature _____

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For internal use only

Report received by:

Report received on:

Action taken:

PLEASE FAX THIS REPORT TO THE RESEARCH GOVERNANCE OFFICE ON 0116 258 4226 OR BY EMAIL TO UOLSPONSOR@LEICESTER.AC.UK