

**Pregnancy Notification Form**

| **Internal Sponsor reference:** | **Centre (if multicentre trial):** |
| --- | --- |
| **R&D reference:** |
| **EudraCT number:** | **Participant number:** |
| **Study Title:** | **Participant initials:** |
| **Do not send identifiable data or source documents with this report** |

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| --- | --- | --- | --- | --- | --- |
| **Initial Report**  |  |  | **Follow Up Report** |  |  |

|  |  |
| --- | --- |
| **Report type:** |  Notification of pregnancy in participant **(please complete all sections of the form).** |
|  |  Notifications of pregnancy in partner of male participant (please complete **sections 6,9,10 and include any other relevant information in section 11).** |
| **1: Maternal information** |
| DOB (dd/mm/yyyy): | Date of last menstrual period: | Expected date of delivery: |
| Method of contraception: | Contraception used as instructed? Yes [ ]  No [ ]  Uncertain [ ]  |
| **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). |
| Maternal |
| Paternal |
| **3: Previous obstetric history** (record both maternal and paternal history; provide details on all previous pregnancies, including miscarriage, stillbirth or maternal termination) |
|  | Maternal | Paternal | Gestation week | Outcome including any abnormalities |
| 1 |  |  |  |  |
| 2 |  |  |  |  |
| 3 |  |  |  |  |
| **4: Drug information** (list all therapies, including study drug, taken prior to and during pregnancy) |
| **Maternal** (list all therapies taken prior to and during pregnancy) |
| Name of drug | Daily dose | Route | Drug started | Drug Stopped | Indication |
|  |  |  | Date | Week of Pregnancy | Tick if ongoing | Date | Week of pregnancy |  |
|  |  |  |  |  |[ ]   |  |  |
|  |  |  |  |  |[ ]   |  |  |
|  |  |  |  |  |[ ]   |  |  |
|  |  |  |  |  |[ ]   |  |  |
| **Paternal** (include only those taken prior to conception) |
| Name of drug | Daily dose | Route | Drug started | Drug stopped | Indication |
|  |  |  | Date | Tick if ongoing | Date |  |
|  |  |  |  |[ ]   |  |
|  |  |  |  |[ ]   |  |
|  |  |  |  |[ ]   |  |
| **5: Prenatal Information**  |
| Have any specific tests, eg amniocentesis, ultrasound, maternal serum AFP, been performed during the pregnancy?Yes [ ]  No [ ]  Uncertain [ ] If yes, please specify test date and results: |
| Test | Date | Result |
|  | **D** | **D** | **M** | **M** | **Y** | **Y** |  |
|  | **D** | **D** | **M** | **M** | **Y** | **Y** |  |
|  | **D** | **D** | **M** | **M** | **Y** | **Y** |  |
| **6: Pregnancy outcome** |
| Abortion: [ ]  Therapeutic [ ]  Planned [ ]  Spontaneous [ ] Please specify the reason and any abnormalities (if known):Date of abortion: | Delivery: [ ]  Normal [ ]  Forceps/Ventouse [ ]  Caesarean [ ] Maternal complications or problems related to birth:Date of delivery: |
| **7: Maternal pregnancy associated events** If the mother experiences an SAE during the pregnancy, please indicate here and complete a SAE form and email to sponsor immediately – pharmaco@abdn.ac.uk |
|  |
| **8: Child outcome** |
|  Normal [ ]  Abnormal [ ]  Stillbirth [ ]  | If any abnormalities, please specify and provide dates |
| Sex Male [ ]  Female [ ]  | Height cm | Weight kg | Apgar scores1 min5 mins10 mins | Head circumference  cm |
| **9: Assessment of seriousness (of pregnancy outcome)** |
| Non serious [ ]  Life-threatening [ ]  Involved in prolonged participant hospitalisation [ ]  Congenital anomaly/birth defect [ ] Results in persistent or significant disability/incapacity [ ]  Other significant medical events [ ] Mother died [ ]  Date of death:Stillbirth/neonate died [ ]  Date of death: |
| **10. Assessment of causality (of pregnancy outcome)** |
| Please indicate the relationship between pregnancy outcome. |
|  Unrelated [ ]  |  Possibly\* [ ]  |  Probably\* [ ]  |  Definitely\* [ ]  |
| If any of the \*fields have been checked, the outcome is considered to be RELATED to the study drug. |
| **11: Additional information** |
|  |
| **12: Information source (person responsible for completing this form)** |
| Name |  |
| Position |  |
| Address |  |
| Signature  |  |
| Date of signature |  |
| **All reports must be signed and dated by the Principal Investigator (PI).****Please email all reports to Sponsor pharmaco@abdn.ac.uk**  |
| **13: Tracking (internal use only)** |
| Report received by |  |
| Report received on  |  |
| Action Taken |  |