

**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** |  |  |

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| **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 | | | | | | | | | | |
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| 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 | |
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| **Paternal** (include only those taken prior to conception) | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name of drug | | Daily dose | | Route | | Drug started | | | | | | | | | Drug stopped | | | | | | | | | | Indication |
| Date | | | | | | | | | Tick if ongoing | | | | | | Date | | | |  |
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| **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 | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **8: Child outcome** | | | | | | | | | | | | | | | | | | | | | | | | | |
| Normal  Abnormal  Stillbirth | | | | | | | | | | | | | If any abnormalities, please specify and provide dates | | | | | | | | | | | | |
| Sex  Male  Female | | | Height  cm | | | | Weight  kg | | | | | | Apgar scores  1 min  5 mins  10 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** | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **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 | | | | | |  | | | | | | | | | | | | | | | | | | | |