**Pregnancy Report Form**

**DO NOT SEND IDENTIFIABLE INFORMATION OR SOURCE DATA WITH THIS REPORT**

|  |
| --- |
| Study Title: |
| Study Reference: |  | Centre ID (if multicentre): |  |
| EudraCT Number: |  | Subject ID: |  |
| R&D Reference (if known): |  | Subject Initials: |  |

1. **Maternal Information**

|  |  |  |  |
| --- | --- | --- | --- |
| Date of Birth:\_\_ \_\_\_ \_\_\_\_DD MMM YYYY | Age yrs/mo: | Date of last menstrual period:\_\_ \_\_\_ \_\_\_\_ DD MMM YYYY | Expected Date of Delivery:\_\_ \_\_\_ \_\_\_\_DD MMM YYYY |
| Method of Contraception: | Contraception Used as instructed:Yes No Uncertain  |

1. **Medical History (Include familial disorders, known risk factors or conditions that may influence the pregnancy outcome. Mark as N/A if there are no known risks):**

|  |
| --- |
|  |

1. **Previous Obstetric History (provide details on all previous pregnancies, including termination or stillbirth)**

|  |  |  |
| --- | --- | --- |
|  | Gestational week | Outcome including any abnormalities |
| 1. |  |  |
| 2. |  |  |
| 3. |  |  |
| 4. |  |  |

1. **Drug Information (list all therapies taken prior to and during pregnancy)**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Drug Names | Daily Dose | Route | Treatment Dates | Indication | Treatment |
| Start | Stop | Start (wk of pregnancy) | Stop (wk of pregnancy |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |

1. **Prenatal Information**

|  |  |
| --- | --- |
| Have any specific tests, e.g. amniocentesis, ultrasound, maternal serum AFP, been performed during the pregnancy so far? | Yes No Not known  |
| If Yes, please specify test date and results:Test type:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Result:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_ \_\_\_ \_\_\_\_ DD MMM YYYY |

1. **Pregnancy Outcome**

|  |  |  |
| --- | --- | --- |
| Delivery: Yes NoIf Yes:Normal Forceps/Ventouse C-section  |  | Abortion: Yes NoIf Yes:Therapeutic Planned Spontaneous  |
| Maternal complications or problems related to delivery: |  | Please specify reason and any (known) abnormalities: |
|  |  |  |

1. **Maternal Pregnancy Associated Events**

|  |
| --- |
| *Please indicate any Serious Adverse Drug Reactions here and report online via Datix:* |

1. **Child Information**

|  |
| --- |
| Neonate:Normal Abnormal Stillbirth *If Abnormal specify any abnormalities:* |
| Sex: Male Female  | Height (cm): | Weight (kg): | Apgar Scores:1 min: \_\_\_\_\_\_\_\_\_5 mins : \_\_\_\_\_\_\_\_10 mins:\_\_\_\_\_\_\_\_ | Head circumference (cm): |
| *Provide copies of any relevant documentation, for additional information use the last page of this template.* |

1. **Assessment of Pregnancy Outcome (seriousness, causality)**

|  |  |
| --- | --- |
| ASSESSMENT OF SERIOUSNESS CRITERIA: Non-serious  Fatality: Mother Neonate  Date:\_\_\_\_\_\_\_\_\_\_\_\_ DD MMM YYYY Involved inpatient hospitalisation (new) Prolonged inpatient hospitalisation Resulted in significant disability/ incapacity Was life-threateningOther Serious Criteria: Congenital anomaly/ birth defect Other significant medical events | ASSESSMENT OF CAUSALITY:*Indicate the relationship between pregnancy outcome and study related procedures or study drug:* Likely related Unlikely related Possibly related Probably related |

1. **Information Source**

|  |  |
| --- | --- |
| Name, Address and Contact details of reporting Investigator:Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Date of Report: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ DD MMM YYYY |

1. **Additional Information**

|  |  |  |  |
| --- | --- | --- | --- |
| For internal use,Report received by: |  | Action Taken: |  |
| Date: |  |  |  |

**ALL REPORTS ARE TO BE SIGNED AND DATED BY THE PRINCIPAL INVESTIGATOR**

For Additional Information: