

|  |
| --- |
| **PREGNANCY ON A CLINICAL TRIAL OF AN INVESTIGATIONAL MEDICINAL PRODUCT** **– FOLLOW UP FORM** |
| Pregnancy on a clinical trial must be recorded and reported to the Sponsor.It is desirable to follow up the pregnancy but consent must be obtained. The forms are complementary to reduce duplication. This should follow the **Notification** formFollow-ups to be completed at the end of the pregnancy and 6 months post birth (if applicable) |

|  |
| --- |
| **1 – Trial Information** |
| 1a) Sponsor |  |
| 1b) Chief Investigator |  |
| 1c) Investigator name (If other site) |  |
| 1d) Study site name |  |
| 1e) EudraCT number |  |
| 1f) R&D number |  |
| 1g) Study Title |  |

|  |
| --- |
| **2 – Participant Information** |
| The participant is ***female*** and has become pregnant while taking part in a clinical trial | *Yes* | *No* |
| The participant is ***male*** whose female partner has become pregnant while ***he*** is on a trial | *Yes* | *No* |
| Has consent been given to follow up the pregnancy? | *Yes* | *No* |

|  |
| --- |
| **3 – Maternal Information** |
| Initials | ID No (if applicable) | DOB | Last menses | Expected Delivery date |
|  |  |  |  |  |
| If participant is male | Initials |  | ID No |  | DOB |  |

|  |
| --- |
| **4 – Pre-Natal Information (Any tests performed and Results)** |
| Amniocentesis | Yes | No | Result |  |
| Ultra sound | Yes | No | Result |  |
| Maternal serum AFP | Yes | No | Result |  |
| Other |  |

|  |
| --- |
| **5 – Pregnancy outcome** |
| Carried to term | Yes | No | Week of delivery |  | Date of delivery |  |
| If yes was the delivery | Normal | Forceps/Ventouse | Caesarean |
| If no was the termination | Spontaneous | Planned | Therapeutic | Termination date |  |
| Was the baby born still born? | *Yes* | *No* |
| Were there any congenital abnormalities at birth? | *Yes* | *No* |
| If yes, please record the details |

|  |
| --- |
| **6 – Child outcome at 6 months** |
| Has a Birth Defect been recorded | *Yes* | *No* |
| If yes, please record the details |

|  |
| --- |
| **7 – Additional Information** |
|  |

|  |
| --- |
| **THIS REPORT MUST BE SIGNED AND DATED BY THE INVESTIGATOR** |
| • Fill in the form and email an electronic copy to: • Print two copies of the completed form, sign and date• Send one signed copy to research & Development • Put one signed copy in your Trial Master File in the Pharmacovigilance section• Receipt will be acknowledged by email  |
| Name of Investigator (if reporting from a participating site) |  |
| Signature |  | Date |  |
| Name of Chief Investigator  |  |
| Signature |  | Date |  |