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| **PREGNANCY ON A CLINICAL TRIAL OF AN INVESTIGATIONAL MEDICINAL PRODUCT – NOTIFICATION 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. The Follow Up form should be used to complete the event |

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| **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 |  |

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| **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* |

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

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| **4 - Contraception** | | | | | |
| Method (or None) |  | Used as instructed | *Yes* | *No* | *Uncertain* |

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| **5 – Previous Obstetric History (continue in section 8 if required)** | |
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| **6 – Previous Medical History** |
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| **7 – Medical Information** | | | | | | |
| 7a) Information about the IMP | | | | | | |
| Drug | Dose | Route | Start Date | Stop date | Week of pregnancy when medication stopped | |
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| 7b) Concomitant Medication at the time of conception | | | | | | |
| Drug | Indication | Dose | Route | Start date | Stop Date | Action taken |
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| **8 – Additional Information** |
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| **THIS REPORT MUST BE SIGNED AND DATED BY THE INVESTIGATOR** | | | |
| • Fill in the form and email an electronic copy to: WHO  • 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 |  |