**Pregnancy on a Clinical Study - Notification Form**

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| * Pregnancy on a clinical research study must be recorded and reported to the Sponsor (Pharmacovigilance monitor).
* It is desirable to follow-up the pregnancy but the mother’s consent must be obtained.
* Please email this form to the rde-tr.RandDSafetyReporting@nhs Safety reporting mailbox within 24hrs of notification of the event.
* Please use in connection with [SOP 22 Safety Reporting](https://rderesearch.co.uk/about/standard-operating-procedures/) and [WI22 Clinical Trial Participants & Pregnancy](https://rderesearch.co.uk/work-instructions/).
* The Follow Up Form should be used to complete the event, [FRM47](https://rderesearch.co.uk/templates-forms/).
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| **Study Detail** |
| **Study Title** |  |
| **Sponsor** |  | **Chief Investigator** |  |
| **Site** |  | **Principal Investigator** |  |
| **R&D Number** |  | **REC number** |  |

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| **Participant Details** ***(Any information regarding female partners of male study participants should be entered in Other Pregnancy Information)*** |
| **Participant Initials** |  | **Participant Study ID** |  |
| **Gender** | Male [ ]  |  Female [ ]  | **Date of Birth** | DD/MM/YYYY |
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| **Has CI been informed?** | Yes [ ]  | No [ ]  | **Was Study Unblinded?** | Yes [ ]  | No [ ]  |
| **Has the mother given consent to follow up the pregnancy?** | Yes | [ ]  No [ ]  |
| **Has this been recorded in the participant’s EPIC record/notes?** | Yes | [ ]  No [ ]  |

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|  **Study Treatment (information about the IMP)** |
| **Drug Name** | **Brand** | **Dose** | **Frequency** | **Route** | **Start Date** | **End date** | **Week of pregnancy when medication stopped** |
|  |  |  |  |  | DD/MM/YYYY | DD/MM/YYYY |  |
|  |  |  |  |  | DD/MM/YYYY | DD/MM/YYYY |  |
|  |  |  |  |  | DD/MM/YYYY | DD/MM/YYYY |  |
| **Most recent cycle number** |  | **Date last treatment given before pregnancy confirmation** | DD/MM/YYYY |

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| **Other Interventional Treatment (e.g. device, procedure)** |
| **Intervention** | **Brand** | **Start Date** | **End date** | **Other Information** |
|  |  | DD/MM/YYYY | DD/MM/YYYY |  |

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| **Concomitant Medication** |
| **Drug name** | **Brand** | **Indication** | **Dose** | **Frequency** | **Route** | **Start Date** | **Ongoing** | **End date** |
|  |  |  |  |  |  | DD/MM/YYYY | Yes [ ]  | No [ ]  | DD/MM/YYYY |
|  |  |  |  |  |  | DD/MM/YYYY | Yes [ ]  | No [ ]  | DD/MM/YYYY |
|  |  |  |  |  |  | DD/MM/YYYY | Yes [ ]  | No [ ]  | DD/MM/YYYY |
|  |  |  |  |  |  | DD/MM/YYYY | Yes [ ]  | No [ ]  | DD/MM/YYYY |
| **Continued on separate sheet?** |  Yes [ ]  | No [ ]  |  |
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| **Contraception** |
| **Method (or none)** |  | **Used as Instructed?** | Yes [ ]  | No [ ]  | Uncertain [ ]  |

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| **Pregnancy Information** |
| **Start date of last menses**DD/MM/YYYY | **Date pregnancy confirmed**DD/MM/YYYY | **Method of diagnosis** | **Anticipated date of childbirth**DD/MM/YYYY | **Mother consented for pregnancy monitoring?** |
|  Yes [ ]  | No [ ]  |

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| **Past Obstetric History** |
| **Date of delivery** | **Gestation****Weeks** | **Mode of delivery** | **Gender** | **Weight (kg)** | **Antenatal problems** | **Postnatal problems** |
| DD/MM/YYYY |  |  | M [ ]  | F [ ]  |  |  |  |
| DD/MM/YYYY |  |  | M [ ]  | F [ ]  |  |  |  |
| DD/MM/YYYY |  |  | M [ ]  | F [ ]  |  |  |  |

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| **Other Pregnancy Information (concurrent conditions, medical history, information regarding female partners of male study participants etc)** |
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| **THIS REPORT MUST BE SIGNED AND DATED BY THE INVESTIGATOR & CI (for Trust sponsored studies)** |
| * Fill in the form, and email an electronic copy of the report to: rde-tr.RandDSafetyReporting@nhs.net
* File the report form in the ISF/TMF in the Pharmacovigilance section.
* File a copy of the report in the Participant’s EPIC record/notes.

**NOTE –** If this notification form is being used for a Hosted Study where no pregnancy reporting procedures have been described remember to update R&D when you update the Sponsor.  |
| **Name of Investigator (for hosted studies)** |  | **Signature** |  | **Date** | DD/MM/YYYY |
|  |  |  |  |  |  |
| **Name of CI (for Trust sponsored studies)** |  | **Signature** |  | **Date** | DD/MM/YYYY |

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| **For Sponsor / R&D Office Use only** |
| **Date event reported** | **DD/MM/YYYY** | **Date event reviewed** | **DD/MM/YYYY** |
| **Has the event been reported as a safety event (AE/SAE/SUSAR)?** | **Yes** [ ]  **No** [ ]  | **If yes, please record the DTX number:** |  |
| **Comments:** |  |