**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](mailto: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 | |
|  | | | | | | |
| **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 |  | | | | | | | | | |
|  | | | | | | | | | | | | | | |
| **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](mailto: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:** | |  | |