**Pregnancy Report Form**

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| **UPMREB CODE:** | | | | |
| **STUDY PROTOCOL TITLE:** | | | | |
| **PRINCIPAL INVESTIGATOR:** | | | | |
| **INITIAL APPROVAL DATE:** | | | | |
| **DATE OF LAST CONTINUING REVIEW APPROVAL:** <dd/Mmm/yyyy>  Reason, if no CRA Approval:   * Pending SJREB Approval * Less than 10 months since last initial approval * No CRA Submission * Others (specify): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | |
| **Version and date of latest approved protocol:** | | | | |
| **Version and date of latest approved ICF:** | | | | |
| **Email:** | **Telephone:** | | **Mobile:** | |
| **STUDY SITE:** | | | | |
| **STUDY SITE ADDRESS:** | | | | |
| **SPONSOR:** | | | | |
| **SPONSOR CONTACT PERSON:** | | | | |
| **Email:** | **Telephone:** | | **Mobile:** | |
| **REPORT SUBMISSION DATE:** (to be filled out by UPMREB) <dd/Mmm/yyyy>   * **Initial report** * **Follow-up report** | | | | |
| 1. **PATIENT INFORMATION**   *In Pregnancy Report Forms, the patient is always the mother. For clinical trials and researches where patients are allocated an alpha-numeric identifier, the appropriate field (‘Patient Initials/Number’) should be populated with this information. In the cases where the patient is the female partner of an enrolled male patient (drug exposure via father), the father’s patient initials/number should be entered for reference. By using the tick boxes ‘father’ / ‘mother’, there is no ambiguity on who is referred to via the patient number.* | | | | |
| **Patient Initials/Number:**  [Father □ / Mother □] | | **Mother initials:** | | |
| **Mother date of birth: <**dd/Mmm/yyyy> | | **Mother height:** cm | | **Mother weight:** kg |

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| 1. **RELEVANT DRUG(S) EXPOSURE BEFORE/DURING PREGNANCY**   *Up to 3 drugs can be entered, if more drugs have to be reported, the page can be re-printed with the mention ‘Supplemental page’ added manually. Information on the IP drug and other relevant drugs including the International Non-proprietary Name (INN - preferred) (or trade name/active substance), daily dose, route of administration, batch number and administration dates should be mentioned. Tick boxes allow identification of whether the mother or the father was taking the drug(s).* | | | |
| **Drug Name** |  |  |  |
| **Daily dose/s & route of administration** |  |  |  |
| **Batch number** |  |  |  |
| **Treatment start date** | **<**dd/Mmm/yyyy> | **<**dd/Mmm/yyyy> | **<**dd/Mmm/yyyy> |
| **Treatment stop date** | **<**dd/Mmm/yyyy> | **<**dd/Mmm/yyyy> | **<**dd/Mmm/yyyy> |
| **Drug taken by** | Father □ / Mother □ | Father □ / Mother □ | Father □ / Mother □ |

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| 1. **ACTION TAKEN IN RESPONSE TO THE PREGNANCY** | | | |
| **Drug Name (from #2)** |  |  |  |
| **Drug maintained** | □ | □ | □ |
| **Drug reduced** | □ | □ | □ |
| **New daily dose** |  |  |  |
| **On** | **<**dd/Mmm/yyyy> | **<**dd/Mmm/yyyy> | **<**dd/Mmm/yyyy> |
| **Drug permanently withdrawn** | □ | □ | □ |
| **On** | **<**dd/Mmm/yyyy> | **<**dd/Mmm/yyyy> | **<**dd/Mmm/yyyy> |
| **Drug interrupted** | □ | □ | □ |
| **From** | **<**dd/Mmm/yyyy> | **<**dd/Mmm/yyyy> | **<**dd/Mmm/yyyy> |
| **To** | **<**dd/Mmm/yyyy> | **<**dd/Mmm/yyyy> | **<**dd/Mmm/yyyy> |
| **Not Applicable** | □ | □ | □ |

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| 1. **PREGNANCY INFORMATION** | | | |
| **Date of 1st day of last menstrual period:** dd/Mmm/yyyy | | **Estimated delivery date:** dd/Mmm/yyyy | |
| **Pregnancy test/s** | | | |
| □ **Positive urine test**  **Date: <**dd/Mmm/yyyy> | □ **Positive blood test**  **Date: <**dd/Mmm/yyyy> | | □ **Positive ultrasound**  **Date: <**dd/Mmm/yyyy> |
| **Pregnancy outcome** | | | |
| Did the patient experience any complication during pregnancy? | | * Yes. Specify: * No * NA | |
| Did the patient give birth to (a) live infant(s)? | | * Yes. Date of delivery **<**dd/Mmm/yyyy> * No. Specify reason: * NA | |
| Was the infant normal at birth? | | * Yes * No. Specify abnormality and reason: * NA | |
| Additional comment on pregnancy/delivery | |  | |

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| 1. **INFANT(S) INFORMATION** | | | | | | |
| **Infant number** | **Sex** | **Length (cm)** | **Weight (g)** | **APGAR score** | **Exposure during breastfeeding** | **Comment** |
| **1** | **F** □ / **M** □ |  |  |  | **Yes** □ / **No** □ |  |
| **2** | **F** □ / **M** □ |  |  |  | **Yes** □ / **No** □ |  |
| **3** | **F** □ / **M** □ |  |  |  | **Yes** □ / **No** □ |  |

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| 1. **RELEVANT MEDICAL HISTORY** *(with focus on relevant prior gynecological/obstetric history)* |

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| **RECOMMENDED ACTION: (for UPMREB use only)**   * NO FURTHER ACTION * REQUEST INFORMATION: (indicate information) * RECOMMEND FURTHER ACTION: (indicate action) * PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE | | | |
| **PRIMARY REVIEWER** |  | Signature |  |
| Date: <dd/Mmm/yyyy> |  | Name | <Title, Name, Surname> |