**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**
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| 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**
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| **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**
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| **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**
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| **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> |