**COVER PAGE**

**Instructions**

Pregnancy must be reported by the investigator to the sponsor/coordinating centre within 24 hours after the site has gained knowledge of the pregnancy. In case of a pregnancy the Pregnancy Event Report Form must be completed, signed and sent by email to SAE.onkologi@skane.se. Please write “NordicTrip pregnancy” in the subject line.

At first hand fill in the form electronically, print, date and sign before you submit the report. An electronic copy of the report can be found at the NordicTrip webpage at [www.nordictrip.se](http://www.nordictrip.se). If an electronic copy is not available, fill in the report on a paper copy.

When the pregnancy report is submitted the reporter shall receive a receipt for confirmation immediately. If no receipt is received please contact the Project Coordinators on [NordicTrip.onkologi@skane.se](mailto:NordicTrip.onkologi@skane.se).

The initial report shall promptly be followed by detailed, written updates if necessary.

|  |  |
| --- | --- |
| Study: NordicTrip/NBG-19-01 | Sponsor: Department of Hematology, Oncology and Radiation Physics, Skåne University Hospital |
| Principal Investigator: | Site name/number: |

Date of report (dd/Mmm/yyyy) \_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_/\_\_\_\_\_\_\_\_\_

Type of report (Tick relevant box)  Initial  Follow-up, no.\_\_\_\_\_\_\_\_\_\_

Pregnancy in a female patient  Pregnancy in a partner of male patient

|  |  |
| --- | --- |
| **Subject information** | |
| **Subject id** | **Sex** |
|  | Female  Male |

|  |  |  |  |
| --- | --- | --- | --- |
| **Mother´s information** | | | |
| **Initials** | **Date of Birth** (Mmm-yyyy) | | **Sex** |
|  |  | | Female  Male |
| **Medical/Familial/Social History**  (i.e. Include alcohol/tobacco and substance abuse; complications of past pregnancy, labor/delivery, fetus/baby; illnesses during this pregnancy; assisted conception: specify; other disorders including familial birth defects/genetic/chromosomal disorders; method of diagnosis consanguinity, etc)) | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Number of previous pregnancies:** | | Full term:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Pre-term:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Outcome of previous pregnancies:**  (Please indicate number of occurrences) | | | | Normal live birth: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Children born with defects: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Spontaneous abortion: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Therapeutic abortion: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Elective abortion: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Stillborn: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| **Mother´s drug exposure information**  Please include medical prescriptions, vaccinations, medical devices, OTC products, pregnancy supplements (such as folic acid, multivitamins) | | | | | | | |
| **Product Name** | **Daily dose** | **Route** | **Date of first use (DD/Mmm/YYYY)** | | **Date of last use (DD/Mmm/YYYY)** | **Indication** | **Contraindicated to pregnancy** |
|  |  |  |  | |  |  |  |
|  |  |  |  | |  |  |  |
|  |  |  |  | |  |  |  |
|  |  |  |  | |  |  |  |
| **Were administrated drugs discontinued due to pregnancy?** | | Yes  No  If yes, which drug? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Father´s information** | | | Father unknown |
| **Initials** | **Date of Birth** (Mmm-yyyy) | | **Age** |
|  |  | |  |
| **Medical/Familial/Social History**  (i.e. Include chronic illnesses: specify, familial birth defects/chromosomal disorders; habitual exposure: specify, alcohol/tobacco; drug exposure: specify, substance abuse and medication use. Please include drug treatment prior to or around the time of conception and/or during pregnancy) | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Pregnancy Event Information** | | | |
| **Date of Last Menstrual Period** (dd/Mmm/yyyy) |  | **Expected Delivery Date** (dd/Mmm/yyyy) |  |
| **Period of exposure in weeks:** |  | **Trimester at date of report** | 1  2  3  Unknown |

|  |  |  |  |
| --- | --- | --- | --- |
| **Was a contraception method used?** | No  Yes  If yes, please specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Do you think there was a failure in contraception?** (non-compliance, mechanical, drug interaction) | No  Yes  If yes, please specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Pregnancy Status** | Pregnancy Ongoing  Live Birth  Stillbirth  Early Termination  Spontaneous abortion\*  Therapeutic abortion\*  Elective abortion\*  Other\*: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  (\* If box is checked, please note reason in “Additional Details” section below) | | |
| **Fetal/Neonatal Status** | Normal  Birth defect (structural/chromosomal disorder)\*  Other (non-structual, premature birth, intrauterine death/stillbirth)\*  (\* If box is checked, please note reason in “Additional Details” section below) | | |
| **Additional Details** | Is there evidence of a defect from a prenatal test?  Yes  No  If yes, indicate which test(s) showed evidence of birth defect:  Ultrasound  Amniocentesis  Maternal Serum-Alpha-Fetoprotein  Chorionic Villi Sampling  Human Chorionic Gonadotropin  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Please specify details of defect(s), disorder(s), and/or other anomaly(ies):  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  What are the defect(s) attributed to:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

|  |  |  |
| --- | --- | --- |
| **Pregnancy outcome, seriousness criteria** | Non-serious  Life-threatening  Other significant medical event  Congenital anomaly/birth defect  Involved or prolonged inpatient hospitalisation  Result in persistent or significant disability/ncapacity  Death of Mother (date of death, DD/Mmm/YYYY):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Death of infant (date of death, DD/Mmm/YYYY): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| **Causality** (Please indicate the relationship between the pregnancy outcome and studydrug) | Capecitabine  Carpoplatin  Cyclophosphamide  Epirubicin  Paclitaxel | Not related  Possibly  Related  Not related  Possibly  Related  Not related  Possibly  Related  Not related  Possibly  Related  Not related  Possibly  Related |
| NA  (normal birth) |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Infant information** | | | | |
| **Gestational weeks at birth or at termination in weeks:** | |  | | |
| **Date of birth or termination:**  (DD/Mmm/YYYY) | |  | | |
| **Sex:** | Female  Male | | **Head circumference in cm:** |  |
| **Length in cm:** |  | | **Weight in g:** |  |
| **Apgar score (0-10) at 1 minute:** |  | | **Apgar score (1-10) at 5 minutes:** |  |
| **Resuscitation required:** | Yes  No | | **Admission to intensive care required:** | Yes  No |
| **If multiple births (e.g. twins), indicate number:**  (Please complete separate form for each child) |  | | **Method of delivery:** | Normal vaginal  Caesarean section  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Birth order:**  (1, 2, 3 etc.) |  | | **Breast-fed** | Yes  No |

|  |  |  |  |
| --- | --- | --- | --- |
| **Has the infant shown any evidence of development delay?** | Yes  No  (if yes, please specify the type of delay)  Motor development: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Language development: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Social/emotional development: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
| **Has the infant experienced serious infection requiring hospitalization?** | Yes  No  If yes, please specify: \_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Is there evidence the infant is immune-comprised?** | Yes  No  If yes, please specify: \_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Has the infant had other relevant illnesses, surgeries or hospitalisations?** | Yes  No  If yes, please specify: \_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Have any congenital malformations been diagnosed since birth?** | Yes  No  If yes, please specify: \_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| **Additional notes** |
|  |

|  |  |
| --- | --- |
| **Contact Details** | |
| **Phone no** |  |
| **Fax no** |  |
| **Email** |  |
| **Country** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Signatures** | | | |
| **Role reporter** |  | **Date**  (dd-Mmm-yyyy) |  |
| **Name reporter** |  | | |
| **Signature** |  | | |
| **Role** | **Investigator** | **Date**  (dd-Mmm-yyyy) |  |
| **Name investigator** |  | | |
| **Signature** |  | | |