Pregnancy Event Report Form

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. 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.

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

Pregnancy Event Report Form

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 a male patient

Subject information	
Subject id	**Sex**
	☐ Female ☐ Male

Mother´s information (to fill in ONLY if the study-subject is the mother)	
Date of Birth (Mmm-yyyy)	
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))	_____ _____ _____ _____ _____

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? _____		
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

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Father´s information (to fill in ONLY if the study-subject is the father)	
Date of Birth (Mmm-yyyy)	
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			
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)		
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/3ncapacity ☐ Death of Mother (date of death, DD/Mmm/YYYY):_____ ☐ Death of infant (date of death, DD/Mmm/YYYY): _____		

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Causality (Please indicate the relationship between the pregnancy outcome and studydrug)	☐ Capecitabine	☐ Not related	☐ Possibly	☐ Related
	☐ Carpoplatin	☐ Not related	☐ Possibly	☐ Related
	☐ Cyclophosphamide	☐ Not related	☐ Possibly	☐ Related
☐ NA (normal birth)	☐ Epirubicin	☐ Not related	☐ Possibly	☐ Related
	☐ Paclitaxel	☐ Not related	☐ Possibly	☐ Related
	☐ Pembrolizumab	☐ Not related	☐ Possibly	☐ Related

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			