Serious Adverse Event Report Form

COVER PAGE

Instructions

SAEs must be reported by the investigator to the sponsor/coordinating centre within 24 hours after the site has gained knowledge of the SAE. In case of an SAE the Serious Adverse Event Report Form must be completed, signed and sent by email to SAE.onkologi@skane.se. Please write "NordicTrip" 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 SAE 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.

Serious Adverse 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._____

Subject information			
Subject id	**Date of Birth** (Mmm-yyyy)	**Sex**	**Arm**
		☐ Female ☐ Male	☐ ddEC ☐ CEX

Serious Adverse Event Information					
SAE Term					
Onset date (dd/Mmm/yyyy)		**Stop date** (dd/Mmm/yyyy)			
Serious Criteria	☐ Death ☐ Life threatening ☐ Hospitalization/Prolonged Hospitalization ☐ Persistent or significant disability/incapacity ☐ Congenital anomaly/Birth Defect ☐ Important Medical Event			**Grade**	☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5
Relationship	Capecitabine Carboplatin Cyclophosphamide Epirubicin Paclitaxel Pembrolizumab	☐ Not related ☐ Not related ☐ Not related ☐ Not related ☐ Not related ☐ Not related	☐ Possibly ☐ Possibly ☐ Possibly ☐ Possibly ☐ Possibly ☐ Possibly	☐ Related ☐ Related ☐ Related ☐ Related ☐ Related ☐ Related	
Action	☐ Delayed ☐ Dose Reduced ☐ Omitted ☐ Discontinued ☐ None				

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Description (Please provide a brief narrative of the SAE. Presenting symptoms, clinical course, treatment etc. or attach extra pages, such as laboratory reports, if applicable).	
Outcome	☐ Not recovered/Not resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Fatal ☐ Unknown

Please add Death Information if applicable	
Date of Death (dd/Mmm/yyyy)	
Autopsy performed	☐ No ☐ Yes
Cause(s) of Death (list primary cause of Death first)	
Was Death related to Study drug(s) (If yes specify study drug)	☐ No ☐ Yes, Specify:
Was Death related to protocol design or procedures (If yes specify procedure)	☐ No ☐ Yes, Specify:

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Contact Details	
Phone no	
Fax no	
Email	

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