**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](http://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](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.\_\_\_\_\_\_

|  |  |  |  |
| --- | --- | --- | --- |
| **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 | Not related  Possibly  Related  Not related  Possibly  Related  Not related  Possibly  Related  Not related  Possibly  Related  Not related  Possibly  Related | | |
| **Action** | Delayed  Dose Reduced  Omitted  Discontinued  None | | | |
| **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: |

|  |  |
| --- | --- |
| **Contact Details** | |
| **Phone no** | **04040** |
| **Fax no** |  |
| **Email** |  |

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