**INSTRUCTIONS:**

**Physician:** complete this form **WITHIN 24 HOURS** and e-mail or fax to IKNL Clinical Research Department:

trialbureau@iknl.nl 088-2346011

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Initial:  Follow up:  Final: | COLOR-III number | Year of Birth  *(yyyy)* | Gender  *(1=male; 2=female)* | SAE onset date  *(dd/mm/yyyy)* |
|  | \_\_\_\_\_\_\_\_\_\_\_ | |\_\_|\_\_|\_\_|\_\_| | |\_\_| | |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_| |

**Hospital………………………..………… Treatment arm:** |\_\_| **Responsible physician: ……………………**

**1. EVENT:**

|  |  |
| --- | --- |
| **Describe the symptoms and give severity grading acc. to CTCAE 4.0\* for the main event. *(\* 1=mild, 2=moderate, 3=severe, 4=life-threatening, 5=fatal)***  **Specify:**  …………………………………………………………………………………………...  …………………………………………………………………………………………...  …………………………………………………………………………………………...  …………………………………………………………………………………………...  **Please give the appropriate medical term which best describes the event:**  …………………………………………………………………………………………...  Date of Onset/Admission (*dd-mm-yyyy*): |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_|  Date of Discharge (*dd-mm-yyyy*): |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_|  Date of Death (*dd-mm-yyyy*): |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_| | **Category:** |\_\_| |
| **1 =** Death |
| **2 =** Life threatening |
| **3 =** Hospitalisation |
| **4 =** Congenital anomaly/birth defect |
| **5** = significant / permanent disability |
| **6 =** other, *specify*:…………. ……………………………… |
|  |

**2. CAUSALITY / STUDY DRUG INFO:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Treatment:** | **Date Surgery/****Date 1st dose:**  after randomization | **Date last dose:** | **Daily dose (mg/Gy):** | **Relation to treatment:\*** | **Action taken regarding to protocol treatment:\*\*** |
| B.v Surgery | |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_| | **Na** | **Na** | |\_\_| | |\_\_| |
| B.v Chemo | |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_| | |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_| | |\_\_||\_\_|.|\_\_| | |\_\_| | |\_\_| |
|  | |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_| | |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_| | |\_\_||\_\_|.|\_\_| | |\_\_| | |\_\_| |

# \* 0=unrelated, 1=unlikely related, 2=possibly related, 3= probably related, 4=definitely related

\*\* 0 = No, 1 = Dose reduced, 2 = Discontinued temporarily, 3 = Discontinued permanently, 4 = Other, specify

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Patient  Seqnr | Date of Birth  *(dd/mm/yyyy)* |  | SAE onset date  *(dd/mm/yyyy)* |
|  | |\_\_|\_\_|\_\_| | | x | x ||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_| |  | |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_| |

**3. MEDICAL HISTORY:**

|  |
| --- |
| **Relevant medical history:**  Please specify if there are circumstances other than trial medication that may have contributed to the SAE  Disease under study including progression |\_\_| 0= No 1= Yes  Concomitant disease or allergy |\_\_| 0= No 1= Yes, specify below  Concomitant medication |\_\_| 0= No 1= Yes, see relevant concomitant medication section  Trial related procedure |\_\_| 0= No 1= Yes, specify below  Other |\_\_| 0= No 1= Yes, specify below  ***Specify:***  …………………………………………………………………………………………...  …………………………………………………………………………………………...  …………………………………………………………………………………………... |

**4. CONCOMITANT MEDICATION/LABDATA:**

|  |  |
| --- | --- |
| **Relevant Concomitant Drugs at time of event:**  (limited to medication that the investigator considers to be possibly  contributing to the current event and exclude those used to treat event) | Relevant **Labtests:** |

**5. RESOLUTION:**

|  |
| --- |
| **Resolution:**...|\_\_|  1 = Resolved  2 = Recovering  3 = Recovered with symptoms  4 = Unchanged  5 = Fatal  **Date of resolution: |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_|** |

**6. REPORTER:**

|  |  |  |
| --- | --- | --- |
| Name + Function: | E-mail: | Telephone or pager: |
|  |  |  |

**Date Initial report: |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_| Signature reporter: ………………..………**

**Date Follow up report: |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_| Signature reporter: ………………..………**

**Date Final report: |\_\_|\_\_||\_\_|\_\_||\_\_|\_\_|\_\_|\_\_| Signature investigator:………………..………**