**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 SAEDisease under study including progression |\_\_| 0= No 1= YesConcomitant disease or allergy |\_\_| 0= No 1= Yes, specify belowConcomitant medication |\_\_| 0= No 1= Yes, see relevant concomitant medication sectionTrial related procedure |\_\_| 0= No 1= Yes, specify belowOther |\_\_| 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 possiblycontributing to the current event and exclude those used to treat event) | Relevant **Labtests:** |

**5. RESOLUTION:**

|  |
| --- |
| **Resolution:**...|\_\_|1 = Resolved2 = Recovering3 = Recovered with symptoms4 = Unchanged5 = 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:………………..………**