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| Public | *🞏 All 🗹 Investigators 🗹 Study Nurse 🗹 Study coordinator 🗹 Paramedics 🞏 Admin Staff*  |
| Document revision history / Changes-Revision Comment |  |

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| --- | --- |
| **SERIOUS ADVERSE EVENT REPORT** |  **SUSAR** (Suspect Unexpected Serious Adverse Reaction):  **YES NO** |
| PROTOCOL NAME: |
| ETHICS COMMITTEE REFERENCE NUMBER: ……………………………. | EUDRACT / SITE N° / PATIENT N° …. - …… - ……. / … / ….  |

**I. REACTION INFORMATION**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. PATIENT INITIALS  | 2.. COUNTRY  | 3. DATE OF BIRTH  | 4. AGE  | 5. SEX  | 6. REACTION ONSET  | 9. CHECK ALL APPROPRIATE |
| (first, last)  |    | Day  | Month  | Year  | Years  |    | Day  | Month  | Year  |  ADVERSEREACTION  |
| 7 DESCRIBE REACTION(S) (including relevant tests/lab data)  |  PATIENT DIED  INVOLVED ORPROLONGEDINPATIENTHOSPITALISATION  INVOLVEDPERSISTENT ORSIGNIFICANTDISABILITY ORINCAPACITY  LIFETHREATENING CONGENITAL ANOMALY/BIRTH DEFECT OTHER MEDICALLY IMPORTANT CONDITION\* |
| 10. MedDRA : SYSTEM ORGAN CLASS LOWEST LEVEL TERM  |
| 11. OUTCOME: DAY/MONTH/YEAR: …. / …. / ….RESOLVED:  RESOLVED WITH SEQUELAE: ONGOING: UNKNOWN: FATAL (+date of death):  |

**II. SUSPECT DRUG(S) INFORMATION**

|  |  |
| --- | --- |
| 12. SUSPECT DRUG(S) (include generic name) | 17. DID REACTIONABATE AFTERSTOPPING DRUG?  YES NO NA  |
| 13. CAUSALITY: CERTAIN PROBABLE POSSIBLE UNLIKELY CONDITIONAL UNASSESSABLE  |
| 14. DAILY DOSE(S)  | 15. ROUTE(S) OF ADMINISTRATION  | 18. DID REACTIONREAPPEARAFTER REINTRODUCTION?  YES NO NA |
| 16. INDICATION(S) FOR USE  |
| 19. THERAPY DATES (from/to)  | 20. THERAPY DURATION  |

**III. CONCOMITANT DRUG(S) AND HISTORY**

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| 21. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)    |
| 22. OTHER RELEVANT HISTORY (e.g. diagnoses, allergies, pregnancy with last menstrual period, etc.)    |

**IV. INVESTIGATOR INFORMATION**

|  |  |
| --- | --- |
| 23. NAME OF REPORTER  | 29. NAME AND ADDRESS OF INVESTIGATOR |
| 24. MFR\*\* CONTROL NO. |  25. DATE RECEIVEDBY MANUFACTURER |
| 26. REPORT SOURCE STUDY LITERATURE HEALTH PROFESSIONAL  REGULATORY AUTHORITY OTHER | 27. SPONSOR USE: REPORT NO. |
| DATE OF THIS REPORT  | 28. REPORT TYPE INITIAL FOLLOW-UP  | INVESTIGATOR / REPORTER SIGNATURE |

\* Requires Intervention to Prevent Permanent Impairment or Damage

\*\* MFR = Manufacturer