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| Author | *Hélène François* | | Reviewer(s) | *Joëlle De Vriese* | Approved by | *Michel Toungouz* |
| 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 | ADVERSE REACTION |
| 7 DESCRIBE REACTION(S) (including relevant tests/lab data) | | | | | | | | | | PATIENT DIED  INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  LIFE THREATENING  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 REACTION ABATE AFTER STOPPING DRUG?  YES NO NA |
| 13. CAUSALITY: CERTAIN PROBABLE POSSIBLE  UNLIKELY CONDITIONAL UNASSESSABLE | |
| 14. DAILY DOSE(S) | 15. ROUTE(S) OF ADMINISTRATION | 18. DID REACTION REAPPEAR AFTER 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 RECEIVED BY 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