(نموذج رقم 2) (Form No. 2)

# CIOMS FORM (SUSAR REPORT)

|  |  |
| --- | --- |
|  |  |
| SUSPECT ADVERSE REACTION REPORT  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

**I. REACTION INFORMATION**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. PATIENT INITIALS(first, last)    | 1a. COUNTRY      | 2. DATE OF BIRTH | 2a. AGEYears    | 3. SEX | 4–6 REACTION ONSET | 8–12 CHECK ALL APPROPRIATE TO ADVERSE REACTION |
| Day   | Month   | Year   |   | Day   | Month   | Year   |
| 7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)      | [ ]  PATIENT DEATH[ ]  INVOLVED OR PROLONGED INPATIENT HOSPITALIATION[ ]  INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY[ ]  THREAT TO LIFE |

|  |  |
| --- | --- |
| 14. SUSPECT DRUG(S) (include generic name)       | 20. DID REACTION ABATE AFTER STOPPING DRUG? |
|  | [ ]  YES [ ]  NO [ ]  NA |
| 15. DAILY DOSE(S)      | 16. ROUTE(S) OF ADMINISTRATION      | 21. DID REACTION REAPPEAR AFTER REINTRO- DUCTION? |
| 17. INDICATION(S) FOR USE      | [ ]  YES [ ]  NO [ ]  NA |
| 18. THERAPY DATES (from/to)      | 19. THERAPY DURATION       |

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

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

|  |
| --- |
| 22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude drugs used to treat reaction) |
| 23. OTHER RELEVANT HISTORY (e.g., diagnostics, allergies, or pregnancy with last month of period, etc.)  |

|  |  |
| --- | --- |
| 24a. NAME AND ADDRESS OF MANUFACTURER |   |
|  | 24b. MFR CONTROL NO. |
| 24c. DATE RECEIVEDBY MANUFACTURER | 24d. REPORT SOURCE [ ]  STUDY [ ]  LITERATURE [ ]  HEALTH PROFESSIONAL  |
| DATE OF THIS REPORT | 25a. REPORT TYPE [ ]  INITIAL [ ]  FOLLOW-UP  |  |

**IV. MANUFACTURER INFORMATION**