CIOMS Form (SAR/SUSAR Report)

CIOMS FORM

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| SUSPECT ADVERSE REACTION REPORT |  | | | | | | | | | | | | | | |
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I. REACTION INFORMATION

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. PATIENT INITIALS  (first, last) | 1a. COUNTRY | 2. DATE OF BIRTH | | | 2a. AGE  Years | 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 DIED  INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY  LIFE THREATENING |

II. SUSPECT DRUG(S) INFORMATION

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| 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 | |

III. CONCOMITANT DRUG(S) AND HISTORY

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

IV. MANUFACTURER INFORMATION

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| 24a. NAME AND ADDRESS OF MANUFACTURER | |  |
|  | 24b. MFR CONTROL NO. |
| 24c. DATE RECEIVED BY MANUFACTURER | 24d. REPORT SOURCE   STUDY  LITERATURE   HEALTH PROFESSIONAL |
| DATE OF THIS REPORT | 25a. REPORT TYPE   INITIAL  FOLLOWUP |  |