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 RECEIVEDBY MANUFACTURER       | 24d. REPORT SOURCE [ ]  STUDY [ ]  LITERATURE [ ]  HEALTH PROFESSIONAL  |
| DATE OF THIS REPORT      | 25a. REPORT TYPE [ ]  INITIAL [ ]  FOLLOWUP  |  |