**SUSPECT ADVERSE REACTION 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  | 1a. COUNTRY  | 2. DATE OF BIRTH  | 2a. AGE  | 3. SEX  | 4-6 REACTION ONSET  | 8-12 CHECK ALL APPROPRIATETO ADVERSEREACTION  PATIENT DIED  INVOLVED OR PROLONGED INPATIENT HOSPITALISATION  INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY  LIFE THREATENING |
| (first, last)  |    | Day  | Month  | Year  | Years  |    | Day  | Month  | Year  |
|  7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)  |

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

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| --- | --- |
| 14. SUSPECT DRUG(S) (include generic name)  | 20. DID REACTIONABATE AFTERSTOPPING DRUG?  YES  NO  NA  |
| 15. DAILY DOSE(S)  | 16. ROUTE(S) OF ADMINISTRATION  | 21. DID REACTIONREAPPEARAFTER REINTRO-DUCTION?  YES  NO  NA  |
| 17. INDICATION(S) FOR USE  |
| 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. diagnoses, allergies, pregnancy with last menstrual 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  FOLLOW-UP  |  |