

**CIOMS FORM**

**FORM 3.3**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. PATIENT INITIALS**  **(first, last)** | 1a. COUNTRY | 2. DATE OF BIRTH | | | 2.a AGE  Years | 3.SEX | 4-6 REACTION ONSET | | | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION  PATIENT DIED INVOLVED OR PROLONGED INPATIENT HOSPITALISATION INVOLVED PERSISTENCE OF SIGNINFICANT DISABILITY OR INCAPACITY  LIFE  THREATENING |
| DAY | MOUNTH | YEAR | DAY | MONTH | YEAR |
| 7 + 13 DESCRIBE REACTION (including test/lab data) REAPPEAR AFTER | | | | | | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| II. SUSPECT DRUG(S) INFORMATION   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | 14. SUSPECT DRUGS(S) (include genetic name) | | | |  | 20. DID REACTION ABATE AFTER STOPPING DRUG?  🞎 YES 🞎 NO 🞎 NA | | 15. DAILY DOSE(S) | | | 16. ROUTES OF ADMINISTRATION |  | 21. DID REACTION  REINTRODUCTION? | | 17. INDICATION(S) FOR USE | | | |  | 🞎 YES 🞎 NO 🞎 N/A | | 18. THERAPY DATE (from/to) |  | 19. THERAPY DURATION | |  |  | |  | III. CONCOMITANT DRUG(S) AND HISTORY | | |  |  | | 22. CONCOMITANT DRUGS(S) AND DATES OF ADMNISTRATION (exclude those used to treat reaction) | | | | | | | 23. OTHER RELEVANT HISTORY (e.g. diagnostics, pregnancy with last month of period, etc.) | | | | | |   IV. MANUFACTURER INFORMATION   |  |  |  |  | | --- | --- | --- | --- | | 24. NAME AND ADDRESS OF MANUFACTURING | |  | 26. REMEARKS | |  | 24b. MFR CONTROL NO. |  | 18. THERAPY DATE (from/to) | | 24c. DATE RECEIVED BY MANUFACTURING | 24d. REPORT SOURCE  STUDY 🞎 LITERATURE  HEALTH PROFESSIONAL |  |  | |  |  |  |  | | DATE OF THIS REPORT | 18. THERAPY DATE (from/to) |  |  | |

1. **REACTION INFORMATION**

|  |  |
| --- | --- |
|  |  |