

**CIOMS FORM**

**FORM 3.3**

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| **1. PATIENT INITIALS****(first, last)** | 1a. COUNTRY | 2. DATE OF BIRTH | 2.a AGEYears | 3.SEX | 4-6 REACTION ONSET | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTIONPATIENT 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 |

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

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| 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

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| 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 |  |  |
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| DATE OF THIS REPORT | 18. THERAPY DATE (from/to) |  |  |

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1. **REACTION INFORMATION**

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