CIOMS FORM

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SUSPECT ADVERSE REACTION REPORT	

I. REACTION INFORMATION

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

	ANOMALY ☐ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S) INFORMATION

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 REINTRODUCTION? ☐ YES☐ NO☐NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

III. CONCOMITANT DRUG(S) AND HISTORY

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

<table>
<tr><td colspan="2">24a. NAME AND ADDRESS OF MANUFACTURER</td><td>26-26a. NAME AND ADRESS OF REPORTER (INCLUDE ZIP CODE)</td></tr>
<tr><td>ORIGINAL REPORT NO.</td><td>24b. MFR CONTROL NO.</td><td></td></tr>
<tr><td>24c. DATE RECEIVED BY MANUFACTURER</td><td>24d. REPORT SOURCE
☐ STUDY
☐ LITERATURE
☐ HEALTH PROFESSIONAL
☐REGULATORY AUTHORITY
☐OTHER</td><td></td></tr>
<tr><td>DATE OF THIS REPORT</td><td>25a. REPORT TYPE
☐ INITIAL
☐ FOLLOW-UP</td><td></td></tr>
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