

CIOMS-I FORM

<b>SUSPECT ADVERSE REACTION REPORT</b>	

**I. REACTION INFORMATION**

1. PATIENT INITIALS (first,last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6. REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION  <input type="checkbox"/> PATIENT DIED  <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION  <input type="checkbox"/> INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY  <input type="checkbox"/> LIFE THREATENING
		Day	Month	Year			Day	Month	Year	
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)										
Narrative: *										

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

14. SUSPECT DRUG 1 of 1 (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCTION?  <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

**III. CONCOMITANT DRUGS AND HISTORY**

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**

24a. NAME AND ADDRESS OF MANUFACTURER		Spontaneous report
	24b. MFR CONTROL NO.	
24c. DATE RECEIVED BY MANUFACTURER	24d. BY MANUFACTURER STUDY LITERATURE HEALTH PROFESSIONAL	
DATE OF THIS REPORT	25a. REPORT TYPE INITIAL <input type="checkbox"/> FOLLOWUP <input type="checkbox"/>	

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<b>CONTINUES PREVIOUS PAGE</b>	1. PATIENT INITIALS (first,last)	24b. MFR CONTROL NO.
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7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)