**CIOMS FORM***

# SUSPECT ADVERSE REACTION REPORT

## I. REACTION INFORMATION

| 1. PATIENT INITIAL | 1a. COUNTRY | 2. DATE OF BIRTH | | | 2a. AGE Years | 3. SEX | 4 - 6 REACTION ONSET | | | 8 - 12 CHECK ALL APPROPRIATE TO ADVERSE REACTION |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Day | Month | Year | | | Day | Month | Year | |
| 7 - 13 DESCRIBE REACTION (S) (including test/lab data)<br><br>Event :<br><br>Comment : | | | | | | | | | | ☐ PATIENT DIED<br>☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION<br>☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY<br>☐ LIFE THREATENING |

## II. SUSPECT DRUG(S) INFORMATION

| 14. SUSPECT DRUG(S) (including generic name) | | 20. DID REACTION ABATE AFTER STOPPING DRUG ?<br>☐ YES ☐ NO ☐ NA |
|---|---|---|
| 15. DAILY DOSE(S) | 16. ROUTE(S) OF ADMINISTRATION | 21. DID REACTION REAPPEAR AFTER REINTRODUCTION ?<br>☐ 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; diagnostics, allergies, pregnancy with last month of period, etc. ...) |

## IV. MANUFACTURER INFORMATION

| 24a. NAME AND ADDRESS OF MANUFACTURER | | ***Subsidiary Reference Number*** |
|---|---|---|
| | 24b. MFR CONTROL N° | **Other references** |
| 24c. DATE RECEIVED BY MANUFACTURER | 24d. REPORT SOURCE<br>☐ STUDY ☐ LITERATURE<br>☐ HEALTH PROFESSIONAL | |
| DATE OF THIS REPORT | 25a. REPORT TYPE<br>☐ INITIAL ☐ FOLLOW-UP | |

## Describe reaction (continuation) :