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|--|--|--|--|--|--|--|--|--|--|--|--|--|
| <b>SUSPECT ADVERSE REACTION REPORT</b> |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

**I. REACTION INFORMATION**

|   |             |                  |       |      |         |        |                     |       |      |   |
|---|-------------|------------------|-------|------|---------|--------|---------------------|-------|------|---|
| 1. PATIENT INITIALS<br>(first/last)                             | 1a. COUNTRY | 2. DATE OF BIRTH |       |      | 2a. AGE | 3. SEX | 4-6. REACTION ONSET |       |      | 8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION<br><br><input type="checkbox"/> PATIENT DIED<br><br><input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALIZATION<br><br><input type="checkbox"/> INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY<br><br><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?                                      |  |
| 17. INDICATION(S) FOR USE                      |                                |  |  |
| 18. THERAPY DATES (from/to)                    | 19. THERAPY DURATION           |  |  |
|  |                                | <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA |  |

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

|                                |                                     |                      |
|--------------------------------|-------------------------------------|----------------------|
| <b>CONTINUES PREVIOUS PAGE</b> | 1. PATIENT INITIALS<br>(first/last) | 24b. MFR CONTROL NO. |
|--------------------------------|-------------------------------------|----------------------|

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)