GUIDELINE ON FILLING THE CIOMS FORM

(PLEASE NOTE: - USE SEPARATE CIOMS FORMS FOR EACH PATIENT.)

I. UNDER SECTION I OF CIOMS FORM. “REACTION INFORMATION”
Please fill appropriate details as described below in the sub-section of section I of CIOMS form. (Sub-section 1, 1a, 2, 2a, 3, 4-6 and 7+13 of CIOMS Form).

<table>
<thead>
<tr>
<th>1. PATIENT INITIALS (first, last)</th>
<th>1a. COUNTRY</th>
<th>2. DATE OF BIRTH</th>
<th>2a. AGE</th>
<th>3. SEX</th>
<th>4-6 REACTION ONSET</th>
<th>8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION</th>
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<tr>
<td></td>
<td></td>
<td>Day</td>
<td>Month</td>
<td>Year</td>
<td>Years</td>
<td>Day</td>
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7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

In Sub-Section 1. PATIENT INITIALS (first, last).
- Please mention the patient initials of the first and last name. Do not use the patient's name, as patient's identity is to be held in strict confidence.

In Sub-Section 1a. COUNTRY.
- Please mention the country of occurrence of the adverse event. Do not enter the country of nationality of the patient or the country where the product is manufactured.

In Sub-Section 2. DATE OF BIRTH (Day, Month, Year).
- Please mention the date of birth of the patient in Day, Month & Year format (DD/MM/YYYY).

In Sub-Section 2a. AGE (Years).
- Please mention the age the patient had attained in years.

In Sub-Section 3. SEX.
- Please mention the sex of the patient.
In Sub-Section 4-6 REACTION ONSET (Day, Month, Year).
  ➢ Please mention the adverse reaction onset date (Adverse event Start date) in Day, Month & Year format (DD/MM/YYYY).

In Sub-Section 7+13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Please fill the adverse reaction details as described below in the sub-section 7+13 of CIOMS Form.
  ➢ Please mention details of the adverse event (AE) and its date of onset. Describe the nature of AE, its location, severity (serious, unexpected etc.) and its characteristics.
  ➢ Please mention the action taken for the adverse event (for e.g. was the drug stopped, continuing).
  ➢ Please mention the outcome of the AE (for e.g. resolved with/ without sequelae, continuing, unresolved, including date of recovery or death, if available). Also please mention the treatment given to the patient for the management of the AE.
  ➢ Please mention the AE Stop date (Reaction stop date). If the patient is hospitalized, then please mention the date of discharge in the hospital discharge summary.

Attach additional page if required, giving reference to the Item No. in the form.

II. UNDER SECTION II OF CIOMS FORM. “SUSPECT DRUG(S) INFORMATION”
Please fill appropriate details as described below in the sub-section of section II of CIOMS form. (Sub-section 14, 15, 16, 17, 18, 19, 20 and 21 of CIOMS Form).

<table>
<thead>
<tr>
<th>II. SUSPECT DRUG(S) INFORMATION</th>
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<tbody>
<tr>
<td>14. SUSPECT DRUG(S) (include generic name)</td>
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<td>15. DAILY DOSE(S)</td>
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<td>16. ROUTE(S) OF ADMINISTRATION</td>
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<tr>
<td>17. INDICATION(S) FOR USE</td>
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<tr>
<td>18. THERAPY DATES (from/to)</td>
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<td>19. THERAPY DURATION</td>
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<tr>
<td>20. DID REACTION ABATE AFTER STopping DRUG?</td>
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<tr>
<td>21. DID REACTION REAPPEAR AFTER REINTRODUCTION?</td>
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</table>

In Sub-Section 14. SUSPECT DRUG(S) (include generic name).
  ➢ Please mention the suspect drug(s) generic name, brand name along with the strength. Give batch numbers of the suspect drug(s) used, if available.
In Sub-Section 15. DAILY DOSE(S).
- Please mention daily dose(s) and frequency details of the suspect drug(s).

In Sub-Section 16. ROUTE(S) OF ADMINISTRATION.
- Please mention route(s) of administration details of the suspect drug(s).

In Sub-Section 17. INDICATION(S) FOR USE.
- Please mention the indication(s) for use of the suspect drug(s).

In Sub-Section 18. THERAPY DATES (from/to).
- Please mention the therapy dates (i.e. therapy start date & therapy stop date) of the suspect drug(s) in the Day, Month & Year format (DD/MM/YYYY).

In Sub-Section 19. THERAPY DURATION.
- Please mention the therapy duration for which the suspect drug(s) was used.

In Sub-Section 20. DID REACTION ABATE AFTER STOPPING DRUG?.
- Please select the appropriate option in this section of the CIOMS form to intimate the status of the adverse reaction after stopping the suspect drug(s), and to know whether the reaction abated after stopping.

In Sub-Section 21. DID REACTION REAPPEAR AFTER REINTRODUCTION?.
- Please select the appropriate option in this section of the CIOMS form to intimate the status of the adverse reaction after reintroduction of the suspect drug(s), and to know whether the reaction reappeared after restarting therapy.

III. UNDER SECTION III OF CIOMS FORM. “CONCOMITANT DRUG(S) AND HISTORY”
Please fill the appropriate details as described below in the sub-section of section III of CIOMS form. (Sub-section 22 and 23 of CIOMS Form).

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.) |
In Sub-Section 22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction).

- Please mention the other medications the patient was taking at the time of occurrence of events apart from suspect drug and their dates of administration? Do not mention drugs used to treat the AE in this section.

In Sub-Section 23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.).

- Please mention the Medical history/ concurrent medical conditions, diagnostics, allergics, pregnancy with last month of period.

IV. UNDER SECTION IV OF CIOMS FORM. “MANUFACTURER INFORMATION”
Please fill the appropriate details as described below in the sub-section of section IV of CIOMS form. (Sub-section 24a, 24b, 24c, 24d & 25a of CIOMS Form).

<table>
<thead>
<tr>
<th>24a. NAME AND ADDRESS OF MANUFACTURER</th>
<th>24b. MFR CONTROL NO.</th>
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<tr>
<th>24c. DATE RECEIVED BY MANUFACTURER</th>
<th>24d. REPORT SOURCE</th>
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<td>STUDY</td>
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<tr>
<th>DATE OF THIS REPORT</th>
<th>25a. REPORT TYPE</th>
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<td>INITIAL</td>
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In Sub-Section 24a. NAME AND ADDRESS OF MANUFACTURER

- Please mention the name and address of manufacturer of the suspect drug(s) and contact number.

In Sub-Section 24b. MANUFACTURER CONTROL NO.

- Please mention the manufacturer control number.

In Sub-Section 24c. DATE RECEIVED BY MANUFACTURER

- Please enter the date on which the adverse reaction details were received by the manufacturer.

In Sub-Section 24d. REPORT SOURCE

- Please select the appropriate option in this section of the CIOMS form for selecting the appropriate report source from whom the adverse reaction details were received.
In Sub-Section 25a. REPORT TYPE
➢ Please select the appropriate option in this section of the CIOMS form for selecting the report type either initial or follow-up.

In Sub-Section. DATE OF THIS REPORT
➢ Please mention the date on which the adverse reaction report was filled by the reporter.

Attach additional page if required, giving reference to the Item No. in the form.