A. Patient Information

1. *Patient initials:* A reporter should only mention the initials of a patient instead of the full name. For e.g.: Madhu Gupta should be written as MG.
2. *Age at time of event or date of birth:* A reporter must report either the date of birth or age of the patient at the time the event or reaction occurred.
3. *Sex:* A reporter must mention the gender of the patient.
4. *Weight:* The weight of the patient should be in kilograms.

B. Suspected Adverse Reaction

5. *Date of reaction started:* A reporter must report the date on which the reaction was first observed.
6. *Date of recovery:* If the reaction recovered, the date on which the reaction recovered should be reported.
7. *Describe reaction:* A reporter must briefly describe the event in terms of nature, localization etc. For example patient developed erythematous maculopapular rash over upper and lower limbs.

C. Suspected Medications

8. The details of suspected medication(s) such as the *drug name (brand or generic name), manufacturer, batch no/lot no, expiry date, dose used, route used, frequency, dates of therapy started and stopped, and indication of use* must be provided by the reporter.
9. *De-challenge details:* A reporter must report the status of de-challenge as:
    - **'Yes'**- if reaction abated or reduced after de-challenge
    - **'No'**- if reaction did not abated after de-challenge
    - **'Unknown'**- if information on de-challenge is not confirmed or not known
    - **'Not Applicable' or 'NA'**- if de-challenge is not possible as in case of anaphylaxis, life threatening events, anaesthetic drugs or where a single dose is given.
    - **'Reduced dose'**- If dose at which the reaction occurred is reduced
      Note: Also mention the reduced dose
10. *Re-challenge details:* A reporter must report the status of re-challenge as:
    - '**Yes'**- if reaction reappeared after re-challenge

- **'No'**- if reaction did not reappear after re-challenge
- **'Unknown'**- if information on re-challenge is not confirmed or not known
- **'Not Applicable' or 'NA'**- if re-challenge is not applicable as in the case of injections.
- **'Re-introduced dose'**- If the drug is reintroduced is it a reduced dose or is it the same dose at which adverse event occurred initially.

11. *Concomitant drugs:* A reporter should include all the details of concomitant drugs including self medication, OTC medication, herbal remedies with therapy dates (start and stop date.)

12. *Relevant tests/ laboratory data:* A reporter must mention any laboratory data (if available) relevant to the adverse event that occurred.

13. *Other relevant history:* A reporter must mention any relevant history pertaining to the patient including pre-existing medical conditions (e.g. allergies, pregnancy, smoking, alcohol use, hepatic/renal dysfunction).

14. *Seriousness of the reaction:* If any event is serious in nature, a reporter must select the appropriate reason for seriousness :

- **'Death'**- if the patient died due to the adverse event
- **'Life-threatening'**- if patient was at substantial risk of dying because of the adverse event
- **'Hospitalisation/prolonged'**- if the adverse event led to hospitalization or increased the hospital stay of the patient
- **'Disability'**- if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions
- **'Congenital anomaly'**- if exposure of drug prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
- **'Required intervention to prevent permanent impairment/damage'**- if medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure
- **'Other'** -when the event does not fit the other outcomes, but the event may put the patient at risk and may require medical or surgical intervention to prevent one of the other outcomes. Examples include serious blood dyscrasias (blood

disorders) or seizures/convulsions that do not result in hospitalization, development of drug dependence or drug abuse

15. *Outcomes:* The reporter must tick the outcome of the event as:

- **'Fatal'**- if the patient dies due to the adverse event
- **'Continuing'**- if the patient is continuing to have the symptoms of the adverse event which occurred
- **'Recovering'**- if the patient is recovering from the existing adverse event
- **'Recovered'**- if the patient has recovered from the event
- **'Unknown'**- if the outcome is not known

D. Reporter

16. *Name and Professional address:* A reporter must mention his/her name and professional address on the form. The identity of the reporter will be maintained confidential

17. *Causality assessment:* The reporter (if trained) must perform the causality assessment.

18. *Date of report:* Mention the date on which he/she reported the adverse event.

NOTE: For quality reporting of ICSRs all the above mentioned fields are essential. In case of incomplete information, the reporter must take care that at least mandatory fields are present. Following are the mandatory fields for a valid case report:

- Patient information: initials, age at onset of reaction, gender.
- Suspected adverse reaction: A reaction term(s), date of onset of reaction
- Suspected medication: Drug(s) name, dose, date of therapy started, indication of use, seriousness, outcome, de-challenge and re-challenge details
- Reporter: Name and address, causality assessment, date of report