Version 02

Adverse Event Reporting

I. PATIENT AND ADVERSE EVENT

1. Patient initials*:	2. DOB (DD/MM/YY)/Age*:	3. Patient gender*	4. Weight	5. Pregnancy*	6. Country*:	7. Medical Record No.
		○ M ○ F		○ No ○ Yes (Term: weeks)		

8. Event description*:	9. Start date (DD/ MM/ YY): 10. End date (DD/ MM/ YY):	11. Criteria of seriousness: ☐ Death, ☐ Life threatening, ☐ Hospitalization or prolongs hospitalization ☐ Disability or permanent damage, ☐ Congenital anomaly/birth defects, ☐ Other medically important condition	12. Please select an outcome for side effect*: ○ Fatal ○ Recovering ○ Recovered ○ Continuing ○ Unknown ○ Other (Please Specify):

13. Did the adverse reaction improve when the drug was discontinued?	14. Did the adverse reaction reappear, when the drug was re-administered?
○ Yes ○ No ○ Unknown ○ Not applicable	○ Yes ○ No ○ Unknown ○ Not applicable

15. Relevant Lab. Data, Diag. Imaging and/or Biopsy (if applicable) Please provide baseline results and normal ranges and copies of reports, if available	Dates

II. SUSPECT DRUG(S) INFORMATION

16. Suspect drug(s) (include generic name) *:	17. Route of administration (Oral, IM, IV, Topical… etc.) *:	
18. Indication(s) for use:	19. Daily dose*:	
20. Therapy dates / duration (start date, end date):	21. Was the drug(s) discontinued? ○ Yes, date ○ No	22. Batch No.

III. CONCOMITANT DRUG(S) AND MEDICAL HISTORY

23. Concomitant drugs and dates of administration:

Product description	dose, route of administration	Therapy start/end date	Indication

24. Other relevant history:

IV. CASE DETAILS

25. Case Narrative

26. Reporting physician's comment

V. PRIMARY REPORTER INFORMATION

27. Reporter name*:	28. Qualification*: ○ Doctor ○ Pharmacist ○ Nurse ○ Patient ○ Other

29. Reporter address (County and City) *:

30. Reporter phone number/email*:

28. Reporter organization:

30. Reporting date (day, month, year) *:

VI. SECONDARY REPORTER INFORMATION

31. Name of SAJA Reporter

32. Department/Affiliation

Note: Points with (*) marks are Mandatory fields

Please fill this reporting form and send via email, post or fax to the Pharmacovigilance department

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