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Patient initials:

Date:

COUNTRY:

REPORT TYPE: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up							
DATE OF BIRTH	AGE	RACE	SEX	HEIGHT	WEIGHT	ONSET DATE	RECOVERY DATE
DD/MM/YYYY			<input type="checkbox"/> Male			DD/MM/YYYY	DD/MM/YYYY
			<input type="checkbox"/> Female				

## ADVERSE EVENT(S) IN MEDICAL TERMS (diagnosis, if possible)

Description of event:

Seriousness criteria
1. The severity of the harm to the victim
2. The culpability of the offender
3. The offender's previous criminal record
4. The offender's attitude towards the victim
5. The offender's attitude towards the law
6. The offender's attitude towards the court
7. The offender's attitude towards the public
8. The offender's attitude towards the community
9. The offender's attitude towards the state
10. The offender's attitude towards the nation
11. The offender's attitude towards the world
12. The offender's attitude towards the universe
13. The offender's attitude towards the gods
14. The offender's attitude towards the spirits
15. The offender's attitude towards the ancestors
16. The offender's attitude towards the future
17. The offender's attitude towards the past
18. The offender's attitude towards the present
19. The offender's attitude towards the time
20. The offender's attitude towards the space
21. The offender's attitude towards the matter
22. The offender's attitude towards the energy
23. The offender's attitude towards the information
24. The offender's attitude towards the knowledge
25. The offender's attitude towards the wisdom
26. The offender's attitude towards the power
27. The offender's attitude towards the wealth
28. The offender's attitude towards the health
29. The offender's attitude towards the life
30. The offender's attitude towards the death
31. The offender's attitude towards the resurrection
32. The offender's attitude towards the judgment
33. The offender's attitude towards the punishment
34. The offender's attitude towards the reward
35. The offender's attitude towards the glory
36. The offender's attitude towards the honor
37. The offender's attitude towards the respect
38. The offender's attitude towards the love
39. The offender's attitude towards the friendship
40. The offender's attitude towards the family
41. The offender's attitude towards the society
42. The offender's attitude towards the culture
43. The offender's attitude towards the religion
44. The offender's attitude towards the politics
45. The offender's attitude towards the economy
46. The offender's attitude towards the environment
47. The offender's attitude towards the nature
48. The offender's attitude towards the animals
49. The offender's attitude towards the plants
50. The offender's attitude towards the minerals
51. The offender's attitude towards the metals
52. The offender's attitude towards the stones
53. The offender's attitude towards the trees
54. The offender's attitude towards the flowers
55. The offender's attitude towards the fruits
56. The offender's attitude towards the vegetables
57. The offender's attitude towards the grains
58. The offender's attitude towards the meats
59. The offender's attitude towards the drinks
60. The offender's attitude towards the clothes
61. The offender's attitude towards the houses
62. The offender's attitude towards the cars
63. The offender's attitude towards the boats
64. The offender's attitude towards the planes
65. The offender's attitude towards the trains
66. The offender's attitude towards the buses
67. The offender's attitude towards the taxis
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173. The offender's attitude towards the motorcycles
174. The offender's attitude towards the cars

Check all appropriate to event

☐ Patient died

☐ Involved or prolonged inpatient hospitalization

☐ Involved persistent or significant disability or incapacity

☐ Life-threatening☐ Congenital anomaly/birth defect

☐ Other significant medical events

## HISTORY :

PATIENT'S RELEVANT MEDICAL HISTORY (e.g. co-existing medical conditions such as disease, allergies, similar experiences)

TEST / LABORATORY FINDINGS (enter only those findings necessary for AE diagnosis or course description)

**SUSPECT DRUG INFORMATION :**

[illegible]

CONCOMITANT DRUGS					
DRUG NAME(S)		DOSE	THERAPY DATES		REASON FOR USE
Brand name	Generic Name		(from ) DD/MM/YYYY	(To) DD/MM/YYYY	

ACTION TAKEN WITH SUSPECT DRUG (mark all as appropriate)		
<input type="checkbox"/> No Action Taken	<input type="checkbox"/> Withdrawn	<input type="checkbox"/> Treatment taken

Did Reaction Disappear After Stopping of Drug?	Did Reaction Reappeared After Restarting of Drug?
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable <input type="checkbox"/> Unknown

OUTCOME OF THE PATIENT/AE			
<input type="checkbox"/> Completely Recovered	Date of recovery:	DD/MM/YYYY	<input type="checkbox"/> Condition still present and unchanged
<input type="checkbox"/> Recovered with sequelae			<input type="checkbox"/> Condition deteriorated
<input type="checkbox"/> Condition improving			<input type="checkbox"/> Death    Autopsy: <input type="checkbox"/> No <input type="checkbox"/> Yes

ASSESSMENT OF CAUSALITY	
<input type="checkbox"/> Probable <input type="checkbox"/> Possible <input type="checkbox"/> Not Related <input type="checkbox"/> Unknown	

REPORTER'S INFORMATION :	
NAME, ADDRESS, TELEPHONE NUMBER AND EMAIL OF REPORTER	DATE OF THIS REPORT DD/MM/YYYY
	<input type="checkbox"/> HCP <input type="checkbox"/> CONSUMER <input type="checkbox"/> OTHER
	Signature:
	<b>Senders Contact details:</b>  India Toll Free : 1-800-267-1222  Email ID: safety@macleodspharma.com