WORLD HEALTH ORGANIZATION

SERIOUS ADVERSE EVENT REPORT

A Serious Adverse Event is an event associated with death, admission to hospital, prolongation of hospital stay, persistent or significant disability or incapacity, or is otherwise life-threatening
THIS FORM SHOULD BE SENT BY FAX TO THE STUDY COORDINATOR (FAX: +41-22 7914171) WITHIN 48 HOURS.

IDENTIFICATION

a) Form Code [S][A][E]

b) Study Number [ ][ ][ ][ ][ ]

c) Centre Number [ ][ ][ ][ ]

d) Subject Identification Code [ ][ ][ ][ ] [ ]

e) AER Report Number [ ][ ]

1. Date event first notified to Investigator ___/___/___ Day Month Year

2. Date of report ___/___/___ Day Month Year

SUBJECT

3. a) Date of birth ___/___/___ Day Month Year
or
b) Age years [ ][ ]

4. Sex
1= Male 2=Female [ ]

5. Weight kg. [ ][ ][ ]

6. Height cm [ ][ ][ ]

7. Occupation _____ [ ][ ] WHO Code

8. Ethnic origin_____ [ ][ ] WHO Code

9. Previous intolerance to medication or devices
1= no 9= unknown
2= yes, specify all medications and devices
_____
_____

ADVERSE

10. Description of event
_____
_____ [ ][ ][ ][ ]
[ ][ ][ ][ ]

11. Date of onset ___/___/___ Day Month Year

12. Date ended ___/___/___ Day Month Year
(888888 if not ended)

13. Duration ***(if less than 24 hours)*** _____:_____ hours min.

14. Hospitalisation (or prolongation of hospitalisation) necessary
1= no 2= yes [ ]

15. Treatment given to manage the event
_____
_____ [ ] [ ][ ][ ]
[ ] [ ][ ][ ]

16. Current status or results

1= complete recovery
2= partial recovery
3= not yet resolved
4= chronic condition or sequelae
5= death
6= unknown [ ]

If "death",

b) Date of death ____/____/____ Day Month Year

c) Cause of death
_____
_____ [ ][ ][ ][ ]
ICD10 CODE

d) Autopsy performed
1= no 2= yes [ ]

Study number | Centre number | Subject ID Code | SAE report number

CASE SUMMARY

Clinical description:

Relevant medical history:

Relevant surgical history:

History of medication:

Other relevant details:

Study number ☐☐☐☐☐ Centre number ☐☐☐☐ Subject ID Code ☐☐☐☐ SAE report number ☐☐

STUDY DRUG OR DEVICE

17. Is exact study group known? ☐

1= no 2= yes

Specify

Name of drug (s) or device(s) _____

Route(s) of administration: _____

_____

Dosage(s) _____

If exact study group not known, for example in a masked study, and randomisation code has not been broken, give details of all relevant study groups (continue on additional pages if necessary)

18. Date drug first taken or device first used ___/___/___ Day Month Year

19. Date drug last taken or device last used ___/___/___ Day Month Year
(888888 if drug or device not discontinued)

20. Measures taken
a) drug or device ☐
1=no change-drug or device continued
2=dose reduced (if relevant)
3=drug or device stopped
9=not applicable
b) immediate effects or symptoms ☐
1= improvement 2= no change
3= aggravation 9=not applicable
c) participation in study ☐
1=continuing 2=discontinued or released from study
3=other

23. Relation of serious adverse event to study drug or device (Principal Investigator's assessment) ☐
1= not related 2= unlikely
3= possibly 4= probably
5= highly probably 9= not assessable, explain

_____

_____

REMARKS

INVESTIGATOR

Name (capital letters) _____

Address _____

_____

Signature_____

Date form completed ___/___/___

21. Concomitant medications at the time of the event

Medication	Daily dose	Date started	Date stopped	Indication

22. Medications used to manage the event
