Adverse event Reporting Form

I. Patient Information

Patient Initials:	**Sex:** □ Male □ Female	**Date of Birth:** (/ /) DD/MM/Year
Weight:	**Height:**	**Country:**

II. Adverse Drug Reaction

Date of Reaction Onset:
(/ /) DD/MM/Year

Description of event (including relevant tests/lab data):

Is the ADR serious: □ Yes □ No
If yes, please specify reasons for seriousness:

□ Death, date (/ /) DD/MM/Year □ Life-threatening □ Hospitalization - initial

□ Hospitalization – prolonged □ Disability □ Congenital abnormality

□ Medically Significant □ Other (please, specify) _____

Outcome of the ADR:

□ Resolved □ Not resolved □ Lost to follow-up □ Unknown

□ Death, death date (/ /) DD/MM/Year:

Autopsy Planned/done □ Yes □ No

Autopsy Report available □ Yes □ No

□ Others (please, specify) _____

Action taken to treat ADR:

□ Medical treatment,(please, specify):

□ Drug stopped □ Drug reduced,(please, specify): _____ □ None

Adverse event Reporting Form

I. Suspected medication

Drug name	Generic name	Daily dose and route	Start date	Stop date	Indication

Did reaction abate after stopping the Drug? ☐YES ☐NO ☐NA

Did reaction reappear after reintroduction? ☐YES ☐NO ☐NA

II. Concomitant medication(s)

Drug name	Generic name	Daily dose and route	Start date	Stop date	Indication

III. Medical history

(e.g. diagnosis, allergies, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.)

Condition	Onset (/ /) DD/MM/Year	Details	Present (Y/N)

IV. Additional information

V. Reporter Information

Reporter Name:	**Profession (specialty)**
Phone/Mobile:	**Fax:**
Date:	**Signature**