

ADR Form Instruction

6. Mention that ADR is serious or not. A serious adverse event or reaction is any untoward medical occurrence that at any dose:
 - a. results in death
 - b. is life-threatening
 - c. required or prolongation of existing hospitalization
 - d. results in persistent or significant disability/incapacity
 - e. constitutes a congenital anomaly or a birth defect
 - f. is medically significant, in that it may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed above
7. Outcome: Mention the outcome of ADR whether it is ongoing, resolved, lost to follow up or unknown.
8. Suspected medication: Enter the name of the medicinal product responsible for the ADR. If there are more than one product, then mention names of all the suspected medicinal products.
9. Concomitant Medications: Indicate the name of the medication/non-drug therapy. Please use the trade name in preference of the treatment. Avoid using abbreviations. Spell the drug name completely and correctly. If it is a combination drug, use the trade name. Record all medications that the Subject is currently taking, or has taken during the 21 days prior to the suspected drug administration.
10. Action taken to treat ADR: Mention whether the suspected drug causing the ADR is stopped or dose has been modified after the ADR or any other concurrent therapy is interrupted due to ADR. Also mention if there is any change in ADR after stopping or reintroduction of suspected drug.
11. Relevant Medical History: Describe pre existing medical conditions those are present before e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction etc.
12. Enter the details of laboratory investigation if done in relevant section.

INVESTIGATOR DETAILS

1. Mention name and contact details of Healthcare professional who has assessed the ADR. Reporter is the person who is reporting this ADR to the sponsor. Mention the details of the Reporter also if he is different from healthcare professional.

SPONSOR DETAILS

1. This is a prefilled section which includes details of company having marketing authorization for the suspected drug.

ADDITIONAL INFORMATION

1. Mention all other information in Additional Information Section which are not included above but are important and relevant to ADR including laboratory investigation, other investigation, medical assessment, etc.