MMC-IRB Serious Adverse Event Report Form 3.1-A

Please use GOOGLE CHROME instead of INTERNET EXPLORER.

For ONSITE SAEs, kindly fill out all information needed. Please forward nine (9) printed copies of this from to IRB office after encoding. Please submit the ONSITE SAEs within seven (7) days after recognition of events.

For OFF SITE SAEs, kindly fill out the ff information only:
1.Date of Onset
2. Event
3. Suspect drug
4. Relationship
5. Country
6. Type of report (E.g. Initial, follow-up, SUSAR listing)
For OFF SITE SAEs, there is no need to print out this form. Instead, kindly forward two (1) printed copy of the original report to the IRB office after encoding.You may submit the OFFSITE SAEs together with the progress report.

Ensure accuracy and right click to print before submitting.

* Required

MMC Protocol Number *

This is a required question

Sponsor Protocol Number *

Protocol Title *

Principal Investigator *
Full name (Surname, First Name, Middle Initial)

Patient Initials
(First, Last)

Date of Birth

mm/dd/yyyy

Age

Gender

Weight (Kg)

Diagnosis/Diagnoses

Country

If Philippines, is it in Makati Medical Center? *

Reaction Onset

Specify the date when the event/reaction occured

mm/dd/yyyy

Describe Reaction(s) including relevant tests/lab data *

Narrate the reaction in detail (e.g. relevant tests, lab data, location of event, interventions given, etc.)

Adverse Event Term *

Identify the event that occurred.

Case Description
Elaborate on the adverse event that occured.

Treatment
Details on the treatment/medication given, if any. Specify dose and duration.

Outcome
Specify the condition of the patient after the treatment was given.

Seriousness *
(Check all appropriate)

- Patient died
- Involved or prolonged in-patient hospitalization
- Involved persistent or significant disability or incapacity
- Life threatening
- Results in congenital anomaly or birth defect
- Other:

Is it an expected reaction?
Based on approved drug information

Causal Relationship (Investigator Reporter) *
Causal Relationship as perceived by the Investigator Reporter

Causal Relationship (Sponsor) *
Causal Relationship as perceived by the Sponsor

Causal Relationship (MMC Investigator) *
Causal Relationship as perceived by the MMC Investigator

Suspect Drug/s (Include generic name) *
Include the name of drug and dose being given.

Daily Dose

Route(s) of administration

- Oral
- Sublingual
- Intravenous
- Intramuscular
- Subcutaneous
- Topical
- Inhalation
- Other:

Indication for use

Therapy date of the Suspect Drug (from)
Specify date the drug was started
mm/dd/yyyy

Was the drug stopped?

- No
- Yes

If YES, Therapy date of the Suspect Drug (to)
Specify date the drug was stopped
mm/dd/yyyy

Did the reaction abate after stopping the drug?

Did the reaction reappear after reintroduction of the same drug? *

Concomitant Drug/s (exclude those used to treat reaction)
Other drug/s being given aside from the study drug. Include inclusive dates. Indicate if none.

Concomitant conditions
Specify other conditions of the patient (e.g. Diagnosis, Allergies, Pregnancy with last menstrual period, etc.) and inclusive dates. Indicate if none.

Other relevant History (e.g. Diagnosis, Allergies, Pregnancy)
Include inclusive dates. Indicate if none. Check below if Unknown.

Unknown

Name of Manufacturer

Address of Manufacturer

Control Number of Manufacturer
Indicate if unknown

Date Received by Manufacturer

mm/dd/yyyy

Report Source

- Study
- Health Professional
- Literature
- Other:

Date Reported

mm/dd/yyyy

Report Type

Remarks

Name of Reporter *

Address of Reporter *

Signature of Investigator (For printed copy)

Submit

Never submit passwords through Google Forms.

100%: You made it.