BATANGAS MEDICAL CENTER
RESEARCH ETHICS REVIEW COMMITTEE

BATANGAS MEDICAL CENTER RERC SAE/SUSAR REPORT (FORM 3.19.1A)

Principal Investigator:	BATMC RERC Code:	
Study Protocol Title:		
Name of the study medicine/device	Report Date: dd/mm/yyyy ☐ Initial ☐ Follow-up Onset date: dd/mm/yyyy	
Sponsor:	Date of first use:	
Patient's Initial/Number:	Age:	☐ Male ☐ Female
Patient's Date of Birth: dd/mm/yyyy	Weight: kg	Height: cm
Relevant medical history and concurrent conditions:		

I. **REACTION INFORMATION:**

_____ (*use CIOMS definition- see Appendix)* List all relevant tests/ lab data:	Check all appropriate to adverse reaction: ☐ Patient died ☐ Involved or prolonged inpatient hospitalization ☐ Involved persistence or significant disability or incapacity ☐ Life threatening

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II. SUSPECT DRUG/S INFORMATION:

<table>
<tr><td colspan="2">Suspect drug/s (include generic name)</td><td>Did reaction abate after stopping drug?
☐ Yes
☐ No
☐ NA</td></tr>
<tr><td>Daily dose/s:</td><td>Route's of administration:</td><td rowspan="3">Did reaction appear after reintroduction?
☐ Yes
☐ No
☐ NA</td></tr>
<tr><td></td><td></td></tr>
<tr><td colspan="2">Indication/s for use:</td></tr>
<tr><td>Therapy date/s: (from/to)</td><td colspan="2">Therapy duration:</td></tr>
<tr><td colspan="3">Is this reaction ☐ Unexpected ☐ Expected</td></tr>
<tr><td colspan="3">Treatment given for Adverse Event:</td></tr>
<tr><td colspan="3">Causality Assessment By Investigator (Using WHO-UMC Causality Assessment System)
☐ Certain
☐ Probable
☐ Possible
☐ Unlikely
☐ Unclassifiable</td></tr>
<tr><td colspan="3">Outcome of reaction/event at the time of last observation:</td></tr>
<tr><td>☐ Recovered
☐ Recovering</td><td>☐ Recovering with sequelae
☐ Not recovering</td><td>☐ Death
☐ Unknown</td></tr>
</table>

III. CONCOMITANT DRUG/S AND HISTORY:

Concomitant drug/s and dates of administration (exclude drug used to treat reaction)
Other relevant history (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

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IV. **MANUFACTURER'S INFORMATION**:

Name and address of manufacturer:		
Manufacturer control no.		
Date received by manufacturer: dd/mm/yyyy	Report source ☐ Study ☐ Literature ☐ Health professional	
Date of this report: dd/mm/yyyy	Report type ☐ Initial ☐ Follow-up	
PRINCIPAL INVESTIGATOR SIGNATURE:		
RECOMMENDED ACTION: *(for BATMC RERC- use only)* ☐ No further action ☐ Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks ☐ Recommend implementation of additional procedures for protecting/ safeguarding participants; ☐ Suspension of enrolment of new participants or research procedures among participants who are currently enrolled (check consistency) ☐ Request information ☐ Recommend suspension of the entire study		
PRIMARY REVIEWER	Signature	_____
Date: <dd/mm/yyyy>	Name	<Title, Given Name, Surname>
CHAIR	Signature	_____
Date: <dd/mm/yyyy>	Name	<Title, Given Name, Surname>

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