Serious Adverse Event Report

CLINICAL STUDY INFORMATION

Sponsor:	Clinical Study Name/Number:
Study Drug/Treatment:	
Report Type: ☐ Initial Report ☐ Follow-up Report	
Investigator:	Email:
Site name and address :	
Telephone:	Facsimile #:

PARTICIPANT INFORMATION

Year of Birth:	Gender: ☐ Male ☐ Female	
Participant Number:	Date of First Dose (DD/MM/YYYY):	Event(s) Onset Date (DD/MM/YYYY):
Ongoing: ☐ Yes ☐ No	Resolution Date (DD/MM/YYYY):	
Event(s) Severity (see definitions): ☐ Mild ☐ Moderate ☐ Severe ☐ Not Applicable		
Description of Event(s):		

SERIOUS ADVERSE EVENT CATEGORY

☐ Death (date): _____
☐ Life-threatening
☐ Disability/Incapacity
☐ Prolongation of Hospitalization
☐ Congenital Anomaly/Birth Defect
☐ Medically Signifcant
☐ Hospitalization

ACTION TAKEN

☐ None
☐ Study drug temporarily stopped
☐ Dose reduced, new dose
☐ Specific therapy for SAE: _____
☐ Study drug permanently stopped

Serious Adverse Events that are experienced by subjects in this study must be reported according to Veritas IRB guidance:
promptly but no later than 10 business days.
Should a Serious Adverse Event occur, please alert us by completing this form and returning it to us by facsimile at 514 336-1142.
In the event that a more complete report may be needed, you will be notified.

Veritas IRB Inc. veritasIRB.com infoIRB@veritasIRB.com Tel.: 1.866.384.4221

OUTCOME

☐ Recovered ☐ Recovered with sequelae ☐ Unknown
☐ Not yet recovered ☐ Fatal

RELATIONSHIP TO STUDY TREATMENT BY THE INVESTIGATOR/SPONSOR

☐ Unrelated ☐ Unlikely ☐ Definite
☐ Possible ☐ Probable

UNEXPECTED / EXPECTED

☐ Unexpected ☐ Expected

TO BE FILLED OUT BY THE INVESTIGATOR/SPONSOR

Are changes recommended to the Study Protocol? ☐ Yes ☐ No

If Yes, have the changes been made? ☐ Yes ☐ No

If No, what are the proposed changes? _____

Are changes recommended to the Informed Consent Documentation? ☐ Yes ☐ No

If Yes, have the changes been made? ☐ Yes ☐ No

If No, what are the proposed changes? _____

_____ _____

Authorized signature *Date*

FOR USE BY VERITAS IRB

Description of action to be taken:

Comments:

_____ _____

Signature (IRB Reviewer) *Date*

Definitions of Adverse Event (AE) Severity and Relationship to Study Treatment

SEVERITY	
Mild	Awareness of signs or symptoms, but easily tolerated
Moderate	Discomfort enough to cause interference with usual activity
Severe	Incapacitating with inability to work or do usual activity

EXPECTED / UNEXPECTED:	
Unexpected	Any adverse experience in which the nature, severity or frequency is not consistent with the current investigator brochure/monograph; or with the risk information described in the investigational plan or protocol or consent form. Unexpected refers to an experience that has not been previously observed. This includes events that are more serious than expected or occur more frequently than expected.
Expected	Any experience that has been identified in nature, severity, or frequency in the current investigator brochure/monograph, investigational plan/protocol and current consent form.

RELATIONSHIP TO STUDY TREATMENT	
Unrelated	The SAE is clearly related to other factors such as the patient's clinical state, therapeutic intervention or concomitant therapy.
Unlikely	The SAE was most probably produced by other factors such as the participant's clinical state, therapeutic interventions or concomitant therapy, and does not follow a known response pattern to the trial product.
Possible*	The SAE: • Follows a reasonable temporal sequence from the time of product administration; and/or • Follows a known response pattern to the trial product; but • Could have been produced by other factors such as the participant's clinical state,therapeutic intervention or concomitant therapy.
Probable*	The SAE: • Follows a reasonable temporal sequence from the time of product administration; and/or • Follows a known response pattern to the trial product; and • Could not have been produced by other factors such as the participant's clinical state, therapeutic intervention or concomitant therapy.
Definite*	The SAE: • Follows a reasonable temporal sequence from the time of product administration; and/or • Follows a known response pattern to the trial product; and • Could not have been produced by other factors such as the participant's clinical state, therapeutic intervention or concomitant therapy; and • Either occurs immediately following trial product administration, or improves on stopping the product, or there is positive reaction at the application site.

**SAEs with a possible, probable or definite relationship to the study treatment will be deemed "related".*

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