

Serious Adverse Event Report

Sponsor:	Clinical Study Name/Number:
Study Drug/Treatment:	
<input type="checkbox"/> Initial Report <input type="checkbox"/> Follow-up Report	
Investigator:	
Site name and address :	
Telephone #: ())	Facsimile #: ())
E-mail:	

Subject Information

Date of Birth (DD/MM/YYYY):	<input type="checkbox"/> Male	<input type="checkbox"/> Female
Subject Number/Initials:		
Date of First Dose (DD/MM/YYYY):		
Event(s) Onset Date (DD/MM/YYYY):		
Ongoing:		<input type="checkbox"/> Yes <input type="checkbox"/> No
Resolution Date (DD/MM/YYYY):		
Event(s) Severity <i>(see definitions)</i> :		
<input type="checkbox"/> Mild	<input type="checkbox"/> Moderate	<input type="checkbox"/> Severe <input type="checkbox"/> Not applicable
Description of Event(s):		

Serious Adverse Event Category

<input type="checkbox"/> Death (date): _____	<input type="checkbox"/> Life-threatening	<input type="checkbox"/> Congenital Anomaly/Birth Defect
<input type="checkbox"/> Hospitalization	<input type="checkbox"/> Disability/Incapacity	<input type="checkbox"/> Medically Significant
	<input type="checkbox"/> Prolongation of Hospitalization	

Action Taken

<input type="checkbox"/> None	<input type="checkbox"/> Dose reduced, new dose
<input type="checkbox"/> Study drug temporarily stopped	<input type="checkbox"/> Study drug permanently stopped
<input type="checkbox"/> Specific therapy for SAE: _____	



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 (Chair/Vice-Chair)

Date



Serious Adverse Events that are experienced by subjects in this study must be reported according to Veritas IRB guidance: promptly but no later than 5 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.

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 patient’s clinical state, therapeutic interventions or concomitant therapy, and does not follow a known response pattern to the trial product.
Possible*	The SAE: <ul style="list-style-type: none"> • 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 patient’s clinical state, therapeutic intervention or concomitant therapy.
Probable*	The SAE: <ul style="list-style-type: none"> • 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 patient’s clinical state, therapeutic intervention or concomitant therapy.
Definite*	The SAE: <ul style="list-style-type: none"> • 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 patient’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”.*

