



**Form 2 - Follow-up Case Report Form
(21 Days Post-BAT Administration)**

BT-010

Cangene Corporation, a subsidiary of Emergent BioSolutions Inc.

Case ID:
(To be completed by Cangene Corporation)

On completion, please email to pharmacovigilance@ebsi.com or fax to: 1-800-768-2281 or 1-204-275-4330

Reporting Physician/Hospital						
Treating Physician Name - Last Name, First Name		Telephone Number	Fax Number	Today's Date (mmm/dd/yyyy) - -		
Hospital Name		City		State	ZIP Code	
Patient Demographic Information						
Patient Initials		Date of birth (mmm/dd/yyyy) - -		Sex Male Female		
Clinical Outcome Information						
Date discharged from ICU: (mmm/dd/yyyy) (If not reported in Form 1)		N/A		Date removed from mechanical ventilation: (mmm/dd/yyyy) (If not reported in Form 1)		
				Patient remained on mechanical ventilation on discharge:		
Date discharged from hospital: (mmm/dd/yyyy) (If not reported in Form 1)		Where was the patient discharged to? Home Nursing home Rehabilitation facility Other (specify):				
Did patient require a tracheostomy? Yes No Unknown		If yes, when was the tracheostomy performed? (mmm/dd/yyyy) - -		Did patient develop pneumonia? Yes No Unknown If 'Yes', please include in the Adverse Event section.		
Did the patient die? Yes No Unknown		If yes:		Date of death (mmm/dd/yyyy): - -		
				Cause of death:		
		Autopsy performed?		Yes No		
		If yes (attach report):		Date (mmm/dd/yyyy): - -		
Did the patient have residual disability upon discharge? Yes No Unknown		If yes, please specify types below: Proximal upper extremity weakness Diminished deep tendon reflexes Distal upper extremity weakness Fatigue Proximal lower extremity weakness Stroke or central nervous system mass or lesion Distal lower extremity weakness Respiratory support (mechanical ventilation) Other (specify):				
Botulism Summary						
Final diagnosis at discharge (please check one) (If changed, or not reported in Form 1)						
Botulism		Tick paralysis		Paralytic shellfish poisoning		
Myasthenia gravis		Eaton-Lambert syndrome		Guillain-Barre syndrome		
Stroke or central nervous system mass or lesion		Other (specify):				
If final diagnosis is Botulism:						
Specify type		Food borne	Wound	Infant	Intestinal colonization	Iatrogenic Unknown
Indicate implicated toxin type:		Type A	Type B	Type C	Type D	
		Type E	Type F	Type G	Unknown	



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Adverse Events List all AEs, NOT already reported in Form 1 - Initial Case Report Form, that occurred from BAT administration to time of discharge.								No Adverse Events Reported			
Description of Event Include information on the following (whether or not it led to an adverse event): • Inadvertent overdoses • Medication errors • Lack of effect	Onset Date & Time (mmm/dd/yyyy hh24:mm)	Serious ✓ if Yes (see definitions)	Use codes below			Resolved Date (mmm/dd/yyyy)	Corrective Treatment Given ¹	Abated after dose stopped or reduced?		Re-appeared after re-introduction?	
			A Severity	B Causality	C Outcome			Yes	No	Yes	No
	- - :					- -		Yes No N/A	Yes No N/A		
	- - :					- -		Yes No N/A	Yes No N/A		
	- - :					- -		Yes No N/A	Yes No N/A		
	- - :					- -		Yes No N/A	Yes No N/A		
	- - :					- -		Yes No N/A	Yes No N/A		
	- - :					- -		Yes No N/A	Yes No N/A		
	- - :					- -		Yes No N/A	Yes No N/A		
	- - :					- -		Yes No N/A	Yes No N/A		
	- - :					- -		Yes No N/A	Yes No N/A		

¹ If 'Yes' complete Concomitant Medications/Corrective Treatments section

See Definitions page	A. Severity/Intensity: 1. Mild 2. Moderate 3. Severe	B. Causality Assessment: 1. Certain 2. Probable/Likely 3. Possible 4. Unlikely 5. Conditional/Unclassified 6. Unassessable/Unclassifiable 7. Unrelated	C. Outcome: 1. Resolved 2. Resolved with Sequelae 3. Resolving/ Ongoing 4. Fatal 5. Unknown
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Concomitant Medications/Corrective Treatments

The following medications and treatments are to be included:

- Medications in use at the time of and since BAT administration (NOT already reported in the **Form 1 - Initial Case Report Form**)
- Treatments of adverse events/reactions
- Antitoxin treatments, other than BAT

Concomitant Medications/ Corrective Treatments	Indication	Treatment of reaction? √ if Yes	Dosage	Frequency	Route	Start Date (mmm/dd/yyyy)	Stop Date (mmm/dd/yyyy)	Ongoing? √ if Yes
						- -	- -	
						- -	- -	
						- -	- -	
						- -	- -	
						- -	- -	
						- -	- -	
						- -	- -	
						- -	- -	
						- -	- -	
						- -	- -	

I have reviewed this Case Report Form and agree that the data reported are accurate, complete and legible.

Any changes or corrections are dated, initialled and explained.

Signature: _____

Date: _____

Reporter's Name: _____

Role: _____



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Definitions

Severity/Intensity Assessment:

- Mild Awareness of a sign or symptom, but subject can tolerate.
- Moderate Discomfort enough to cause interference with normal daily activity.
- Severe Resulting in an inability to do work or do usual daily activity.

Causality (Relatedness) Assessment of Adverse Event(s) (AEs):

The evaluation of any event in relationship to drug administration.
As per the WHO-UMC causality assessment system, the following definitions are used to assess relatedness of the adverse events:

Certain	Event or laboratory test abnormality, with plausible time relationship to drug intake. Cannot be explained by disease or other drugs. Response to withdrawal plausible (pharmacologically, pathologically). Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon). Rechallenge satisfactory, if necessary.
Probable/Likely	Event or laboratory test abnormality, with reasonable time relationship to drug intake. Unlikely to be attributed to disease or other drugs. Response to withdrawal clinically reasonable. Rechallenge not required.
Possible	Event or laboratory test abnormality, with reasonable time relationship to drug intake. Could also be explained by disease or other drugs. Information on drug withdrawal may be lacking or unclear.
Unlikely	Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible). Disease or other drugs provide plausible explanations.
Conditional/ Unclassified	Event or laboratory test abnormality. More data for proper assessment needed, or additional data under examination.
Unassessable/Unclassifiable	Report suggesting an adverse reaction cannot be judged because information is insufficient or contradictory. Data cannot be supplemented or verified.
Unrelated	There is no established relationship between the occurrence of an adverse event and the concomitant or previous intake of a medicinal product.

Seriousness criteria

A serious adverse event (experience) or reaction is any untoward medical occurrence that at any dose:

- Results in death** **Is life-threatening**
- Requires inpatient hospitalization or prolongation of existing hospitalization** **Is a congenital anomaly/birth defect**
- Results in persistent or significant disability/incapacity** **Is medically important**

NOTE: The term "life-threatening" in the definition of "serious" refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

Medical and scientific judgment should be exercised in deciding whether expedited reporting is appropriate in other situations, such as important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also usually be considered serious.