CRF COMPLETION GUIDELINES FOR BT-010 REGISTRY

Botulinum Antitoxin Patient Registry for the Evaluation of Safety and Clinical Outcomes of Pediatric and Adult Patients Following BAT® Treatment for Confirmed or Suspected Exposure to Botulinum Toxin

Registry Website http://botulismantitoxin.info/

CANGENE

Cangene Corporation, a subsidiary of Emergent BioSolutions Inc.

Form 1 - Initial Case Report Form

(See CRF Completion Guide for Instructions)

BT-010

Case ID: Assigned by Cangene

(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

Patient Demographic Information

Patient Initials	Date of birth (mmm/dd/yyyy)	Sex	Weight
	- -	☐ Male ☐ Female	☐ lbs ☐ kg

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Unknown

Race (check all that apply): ☐ African American/Black ☐ American Indian ☐ Asian ☐ Pacific Islander ☐ Unknown ☐ Alaska Native ☐ White ☐ Other (specify):

BAT Dosing information

Dose	Volume	Lot Number	Rate of Infusion	Infusion Start Date/Time (mmm/dd/yyyy hh24:mm)	Infusion End Date/Time (mmm/dd/yyyy hh24:mm)
See below	See below	e.g. 11300324 See back of vial	0.5 ☒ mL/min ☐ mL/hr	FEB - 20 - 2016 13 : 00	FEB - 20 - 2016 13 : 30
			1.0 ☒ mL/min ☐ mL/hr	FEB - 20 - 2016 13 : 31	FEB - 20 - 2016 14 : 01
			2.0 ☒ mL/min ☐ mL/hr	FEB - 20 - 2016 14 : 32	FEB - 20 - 2016 17 : 00

Vital Signs Monitoring (Pre- & Post- BAT Administration)

Date (mmm/dd/yyyy) - -	Pre-Dose	Post-Dose (preferable during the first 6-8 hours and up to 24 hours post infusion)							
Time (hh24:mm):	:	:	:	:	:	:	:	:	:
Temperature	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F
Blood Pressure									
Pulse (bpm)									

Date (mmm/dd/yyyy) - -	Post-Dose								
Time (hh24:mm)	:	:	:	:	:	:	:	:	:
Temperature	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F	☐ °C ☐ °F
Blood Pressure									
Pulse (bpm)									

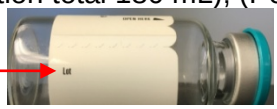
Patient Initials: Must be written in **BLOCK LETTERS;** Initials are first, middle and last names (i.e. **FRANK MICHAEL LEE = FML**).
If last name is hyphenated use both last names (no middle initial) (i.e. **FRANK LEE-MANN= FLM**).
If no middle name, use a DASH (-) (i.e. **FRANK LEE= F-L**)

Birth Date: Is recorded as MMM.DD.YYYY **(JAN.01.2016)**

Ethnicity/Race: See "Ethnicity and Race" next page; Check the correct box(es).

BAT Dosing Information: (see Package Insert):

- **Dose**: e.g. (Adult) 1 vial; (Pediatric 1 – 17 yrs) 20% - 100% of adult 1 vial dose
- **Volume**: e.g. (Adult) 18 mL BAT in 162 mL normal saline (1:10 dilution total 180 mL); (Peds 1 – 17 yrs): 20% - 100% of adult dose
- **Lot Number**: Found on **back** of vial



- **Rate of Infusion**: **see Table** on page 4 of completion guidelines

Vital Signs: Time is recorded using a 24 hour clock; Date is recorded as MMM.DD.YYYY **(JAN.01.2016)**

- **Pre-Dose** vitals are taken **just before** BAT infusion
- **Post-Dose** vitals during first 6-8 hours **after** BAT infusion (up to 24 hours)

ETHNICITY AND RACE

The minimum categories for ***RACE*** are defined as follows:

White: A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Black and African American: A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

Asian: A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.

Native Hawaiian: A person having origins in any of the original peoples of Hawaii Islands.

American Indian: A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliations or community attachment.

Alaska Native: A person having origins in any of the original peoples of Alaska and who maintains tribal affiliation

Pacific Islander: A person having origins in any of the original peoples of other Pacific Islands.

Other: A person who does not fall into a category listed above.

The categories for ***ETHNICITY*** are defined as follows:

Hispanic or Latino: A person of Cuban, Mexican, Puerto Rican, South or Central American, or other Spanish culture or origin, regardless of race. The term "Spanish origin" can be used in addition to "Hispanic or Latino."

Not Hispanic or Latino: A person who does not fall into the category above.

BAT PACKAGE INSERT DOSING TABLE

Patient Group	Dose	Starting Infusion Rate (first 30 minutes)	Incremental Infusion Rate if Tolerated (every 30 minutes)	Maximum Infusion Rate
Adults (≥ 17 years)	One vial	0.5 mL/min	Double the rate	2 mL/min
Pediatric (1 year to <17 years)	20 – 100% of adult dose	0.01 mL/kg/min Do not exceed the adult rate	0.01 mL/kg/min	0.03 mL/kg/min Do not exceed the adult rate
Infants (< 1 year)	10% of adult dose regardless of body weight	0.01 mL/kg/min	0.01 mL/kg/min	0.03 mL/kg/min

For dosing calculation, refer to current approved Package Insert 08/2015

CANGENE

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Form 1 - Initial Case Report Form

BT-010

Case ID: Assigned by Cangene

(To be completed by Cangene Corporation)

Adverse Events
Additionally, include information on inadvertent BAT overdoses or BAT medication errors.

1 ☐ No Adverse Events Reported

Description 2	Onset Date & Time 3 (mmm/dd/yyyy hh24:mm)	Serious √ if Yes (see definitions)	Use codes below: A Severity	B Causality	C Outcome	Resolved Date (mmm/dd/yyyy)	Treat-ment Given[1]	Abated after dose stopped or reduced?	Re-appeared after re-introduction?
Allergic reaction	Jan - 01 - 2016 15 : 30	☐	1	3	1	Jan - 01 - 2016	☑	☐Yes ☐No ☐N/A	☐Yes ☐No ☐N/A
	- - :	4	5			- -	☐	☐Yes ☐No ☐N/A	☐Yes ☐No ☐N/A
	- - :	☐				- -	☐	☐Yes ☐No ☐N/A	☐Yes ☐No ☐N/A
	- - :	☐				- -	☐	☐Yes ☐No ☐N/A	☐Yes ☐No ☐N/A

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

[1] If checked complete Concomitant Medications/Corrective Treatments section

List all adverse events (if applicable) post BAT infusion.

1. Check "NO" if there are NO Adverse Events for this patient and proceed to next section.
2. **Description:** This should be a diagnosis, not a symptom (e.g., rash and bronchoconstriction should be recorded as hypersensitivity reaction). Be as specific as possible (for example, not "abdominal pain" but upper abdominal pain).
3. **Onset Date:** The date the AE started MMM.DD.YYYY (e.g., JAN.01.2016)
4. **Serious:** Check the box if the event:
   - Results in death
   - Required inpatient hospitalization or prolongation of existing hospitalization
   - Results in persistent or significant disability/incapacity
   - Is life-threatening
   - Is a congenital anomaly/birth defect
   - 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.
5. **Assessments of A, B, & C:**

   A: Severity: Enter the number which corresponds to the severity of the event in column A

   1. Mild: Awareness of a sign or symptom but patient can tolerate
   2. Moderate: Discomfort enough to cause interference with normal daily activity
   3. Severe: Resulting in an inability to do work or do usual daily activity

   B: Causality: Enter the number which corresponds to the causal relationship of the adverse events and the BAT in column B. Must be assigned by a physician.

   Indicate suspected assessment of causal relationship to BAT based on the following:

   - **Related**: There is a reasonable possibility that the AE was caused by BAT. "Reasonable possibility" is meant to convey in general that there are facts (evidence) or arguments to suggest a casual relationship
   - **Unrelated**: The AE is clearly/ most probably caused by other etiologies such as the patient's underlying condition, therapeutic intervention or concomitant therapy, or the delay between administration of the product and the onset of the AE is incompatible with a causal relation, or the AE started before the administration of the product.

C: **<u>Outcome</u>: Enter the number which corresponds to the outcome in column C**

1. **<u>Resolved/ Recovered</u>**: The AE was resolved
2. **<u>Resolved with Sequelae</u>**: The acute condition of the AE was resolved but the patient continues with complications
3. **<u>Resolving/Ongoing</u>**: The AE is getting better but still ongoing
4. **<u>Fatal</u>**: Patient death due to the AE or other conditions
5. **<u>Unknown</u>**: No information on the outcome of the AE. (i.e.: patient has transferred to another facility)

<u>FOLLOWING BAT ADMINISTRATION</u>, did the patient experience any of the following reactions? **If any reactions were observed, the DIAGNOSIS is to be included in the Adverse Events table above.**						☐ No Reactions Observed
Description	**Occurrence**					
Fever /Febrile reaction >1°C over baseline	☐ Yes ☐ No ☐ Unknown					
Chills/Rigors	☐ Yes ☐ No ☐ Unknown					
Bradycardia < 60 bpm	☐ Yes ☐ No ☐ Unknown	If 'yes'	Heart Rate:	bpm		
Tachycardia > 100 bpm	☐ Yes ☐ No ☐ Unknown	If 'yes'	Heart Rate:	bpm		
Hemodynamic Instability	☐ Yes ☐ No ☐ Unknown					
Allergic Reaction	☐ Yes ☐ No ☐ Unknown	If 'yes', Signs & symptoms:	☐ Anaphylaxis ☐ Urticaria ☐ Hypotension	☐ Angioedema ☐ Bronchoconstriction ☐ Syncope	☐ Rash ☐ Flushing ☐ Other:	
Serum sickness	☐ Yes ☐ No ☐ Unknown	If 'yes', Signs & symptoms:	☐ Polyarthralgia ☐ Lymphadenopathy	☐ Rash ☐ Other:	☐ Myalgia	

<u>NOTE:</u> ***Check yes <u>only</u> if the event occurred <u>AFTER</u> BAT administration. For any items checked as "YES" please complete the adverse event section.***

<u>Example:</u> Do not check yes if tachycardia was noted at baseline **prior** to BAT treatment if it was not worsened by the BAT administration.

CANGENE

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Form 1 - Initial Case Report Form

BT-010

Case ID: Assigned by Cangene

(To be completed by Cangene Corporation)

Clinical Information

Is patient symptomatic? ☐ Yes ☐ No ☐ Unknown	Onset Date & Time	(mmm-dd-yyyy hh24:mm)	Neurologic Symptom Onset	(mmm-dd-yyyy)	Date First Sought Medical Care	(mmm-dd-yyyy)

Vital Signs (upon presentation): Temperature ☐ °C ☐ °F Blood Pressure (mmHg) / Heart Rate(beats/min) Respiration Rate(breaths/min)

Date and time of exposure to botulism toxin (mmm/dd/yyyy hh:mm): ☐ Actual ☐ Presumed ☐ Unknown

Hospitalized? ☐ Yes ☐ No	Admission date (mmm-dd-yyyy):	Discharge date:
Patient admitted to ICU? ☐ Yes ☐ No	If yes, admission date (mmm-dd-yyyy):	Discharge date:
Patient required mechanical ventilation? ☐ Yes ☐ No	If yes, start date (mmm-dd-yyyy):	Cessation date:

Diagnosis: ☐ Botulism ☐ Tick paralysis ☐ Paralytic shellfish poisoning ☐ Myasthenia gravis ☐ Eaton-Lambert syndrome ☐ Guillain-Barre syndrome ☐ Stroke or central nervous system mass or lesion ☐ Other (specify):

Botulism Antitoxin (BAT) Administration Information

Has the patient had any previous treatment with equine blood products? ☐ Yes ☐ No ☐ Unknown

Were any pre-medications given? ☐ Yes ☐ No

If yes, indicate type and include details in the Concomitant Medications section below ☐ Corticosteroid ☐ Antihistamine ☐ Analgesic/antipyretic ☐ Other (specify):

Neuromuscular Examination	Right	Left	Deep Tendon Reflexes	Right	Left
Proximal Upper Extremity			Biceps/Triceps		
Distal Upper Extremity			Brachial		
Proximal Lower Extremity			Patellar		
Distal Lower Extremity			Ankle		

0 = No evidence of contractility
1 = Slight contractility, no movement
2 = Full range of motion, gravity eliminated
3 = Full range of motion, with gravity
4 = Full range of motion, against gravity, some resistance
5 = Full range of motion, against gravity, full resistance

0 = No Response
1 = Sluggish or diminished
2 = Active or expected response
3 = More brisk than expected, slightly hyperactive
4=Brisk, hyperactive, with intermittent or transient clonus

If muscle weakness/paralysis present, describe progression:
☐ Ascending, ending with cranial nerves ☐ Descending, beginning with cranial nerves ☐ Other (specify): ☐ None ☐ Unknown

Form 1 - Initial Case Report Form
Version 3.0 dated Feb , 2016

Page 3 of 6

Clinical Information:

- Is patient symptomatic (*for botulism*)?
- Date First Sought Medical Care (*for symptoms*)
- Vital signs upon presentation (*at treating facility*) - Please be consistent throughout when checking either °C or °F.

Discharge/Cessation Date: If not applicable indicate N/A

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Symptoms (check all that apply)	Yes	No	Symptom	Yes	No
Nausea	☐	☐	Thick tongue	☐	☐
Vomiting	☐	☐	Change in sound of voice	☐	☐
Abdominal pain	☐	☐	Hoarseness	☐	☐
Diarrhea	☐	☐	Dry Mouth	☐	☐
Constipation	☐	☐	Dysphagia (difficulty swallowing)	☐	☐
Blurred vision	☐	☐	Shortness of breath	☐	☐
Diplopia (double vision)	☐	☐	Subjective weakness	☐	☐
Dizziness	☐	☐	Fatigue	☐	☐
Slurred speech	☐	☐	Paresthesia (abnormal sensation, e.g. numbness)	☐	☐
Other (specify):					

Physical Examination Findings	Yes	No		Yes	No
Alert and oriented	☐	☐	Pupils non-reactive	☐	☐
Extra-ocular palsy (paralysis of eye muscles)	☐	☐	If yes, is it bilateral	☐	☐
If yes, is it bilateral	☐	☐	Facial paralysis	☐	☐
Ptosis (drooping eyelids)	☐	☐	If yes, is it bilateral	☐	☐
If yes, is it bilateral	☐	☐	Palatal weakness	☐	☐
Pupils dilated	☐	☐	If yes, is it bilateral	☐	☐
If yes, is it bilateral	☐	☐	Impaired gag reflex	☐	☐
Pupils constricted	☐	☐	Sensory deficit(s)	☐	☐
If yes, is it bilateral	☐	☐	If yes, specify		
Other (specify):					

Concomitant Medications/Corrective Treatments

The following medications and treatments are to be included:

- Medications in use at the time of BAT administration
- Medications given as pre-treatments to the antitoxin treatment
- Treatments of adverse events/reactions including hemodynamic instability treatments and procedures

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
		☐				- -	- -	☐
		☐				- -	- -	☐
		☐				- -	- -	☐

Symptoms:

- Check all that apply for the patient and indicate any other symptoms not listed in the area provided.

Concomitant Medications (Con Med): Include those given as pre-treatment **and** in use at time of BAT Administration. Additional con meds can be written on separate sheet if more room is needed.

- **Con Med/Corrective Treatment:** If possible provide the generic name of the drug.
- **Indication:** This should ideally be a diagnosis, not a symptom (if possible) (i.e. runny nose, fever = cold).
- **Dose:** The quantity of the con med administered to the patient
- **Frequency (Doses per day):** The number of times the con med is administered to the patient.
- **Route:** Route of administration of the con med.
- **Ongoing:** Check only if no stop date for con med.

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Form 1 - Initial Case Report Form

BT-010

Case ID: Assigned by Cangene

(To be completed by Cangene Corporation)

Medical History

Prior botulism diagnosis?	If yes, date (mmm/dd/yyyy)	Medications used in previous 30 days that could cause neuromuscular paralysis:
☐ Yes ☐ No ☐ Unknown	- -	☐ Myobloc (toxin type B) ☐ Aminoglycoside (e.g.gentamicin, tobramycin) ☐ None ☐ Unknown ☐ Botox (toxin type A) ☐ Anticholinergic ☐ Other (specify):

Does the patient have prior medical history? ☐ Yes ☐ No If yes, provide details below

Please include relevant medical history, risk factors for tachycardia, bradycardia, neurological impairment, hypersensitivity reactions and known allergies	Start Date (mmm/dd/yyyy)	Stop Date (mmm/dd/yyyy)	Ongoing? √ if Yes
	- - ☐ Unknown	- - ☐ Unknown	☐
	- - ☐ Unknown	- - ☐ Unknown	☐
	- - ☐ Unknown	- - ☐ Unknown	☐
	- - ☐ Unknown	- - ☐ Unknown	☐
	- - ☐ Unknown	- - ☐ Unknown	☐
	- - ☐ Unknown	- - ☐ Unknown	☐

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

Medical History:

- Record all relevant medical history, including syndromes and complications known.
- Complete the MONTH/DAY/YEAR for **Start** and **Stop** dates, if known.
- Check the box if still ongoing.

- Medications used in previous 30 days that could cause neuromuscular paralysis (*prior to admission*)

Reporting Physician/Hospital

- Section to be fully completed and signed accordingly.

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

BT-010

Case ID: Assigned by Cangene
(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) FEB - 20 - 2016 ☐ N/A

Date removed from mechanical ventilation: (mmm/dd/yyyy) (If not reported in Form 1) - - ☐ N/A
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
- ☐ Distal upper extremity weakness
- ☐ Proximal lower extremity weakness
- ☐ Distal lower extremity weakness
- ☐ Other (specify):
- ☐ Diminished deep tendon reflexes
- ☐ Fatigue
- ☐ Stroke or central nervous system mass or lesion
- ☐ Respiratory support (mechanical ventilation)

Botulism Summary

Final diagnosis at discharge (please check one)
(If changed, or not reported in Form 1)

- ☐ Botulism
- ☐ Myasthenia gravis
- ☐ Stroke or central nervous system mass or lesion
- ☐ Tick paralysis
- ☐ Eaton-Lambert syndrome
- ☐ Other (specify):
- ☐ Paralytic shellfish poisoning
- ☐ Guillain-Barre syndrome

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

This form is to be completed either 21 days post-BAT administration, or upon discharge or death of patient

Clinical Outcome Information - Complete as much information as possible.

If you've already reported this information in Form 1, **circle** "reported in Form 1" (as shown).

Did patient develop pneumonia? If the patient developed pneumonia post BAT administration, enter the details in the adverse event section. If the pneumonia started prior to BAT and was not exacerbated by the BAT, state that pneumonia is not to be considered an adverse event.

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

BT-010

Case ID: Assigned by Cangene

(To be completed by Cangene Corporation)

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: A Severity	B Causality	C Outcome	Resolved Date (mmm/dd/yyyy)	Corrective Treatment Given [1]	Abated after dose stopped or reduced?	Re-appeared after re-introduction?
	- - :	☐				- -	☐	☐ 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
	- - :	☐				- -	☐	☐ Yes ☐ No ☐ N/A	☐ Yes ☐ No ☐ N/A

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

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

INSTRUCTIONS ON NEXT PAGE

ADVERSE EVENTS (AEs)

List all adverse events (if applicable) post BAT infusion.

1. Check "NO" if there are NO Adverse Events for this patient and proceed to next section.
2. **Description:** This should be a diagnosis, not a symptom (e.g., rash and bronchoconstriction should be recorded as hypersensitivity reaction). Be as specific as possible (for example, not "abdominal pain" but upper abdominal pain).
3. **Onset Date:** The date the AE started MMM.DD.YYYY (e.g., JAN.01.2016)
4. **Serious:** Check the box if the event:
   - Results in death
   - Required inpatient hospitalization or prolongation of existing hospitalization
   - Results in persistent or significant disability/incapacity
   - Is life-threatening
   - Is a congenital anomaly/birth defect
   - 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.
5.

   Assessments of A, B, & C:

   A: Severity: Enter the number which corresponds to the severity of the event in column A

   1. Mild: Awareness of a sign or symptom but patient can tolerate
   2. Moderate: Discomfort enough to cause interference with normal daily activity
   3. Severe: Resulting in an inability to do work or do usual daily activity

   B: **Causality: Enter the number which corresponds to the causal relationship of the adverse events and the BAT in column B**. Must be assigned by a physician.

   Indicate suspected assessment of causal relationship to BAT based on the following:

   - **Related**: There is a reasonable possibility that the AE was caused by BAT. "Reasonable possibility" is meant to convey in general that there are facts (evidence) or arguments to suggest a casual relationship
   - **Unrelated**: The AE is clearly/ most probably caused by other etiologies such as the patient's underlying condition, therapeutic intervention or concomitant therapy, or the delay between administration of the product and the onset of the AE is incompatible with a causal relation, or the AE started before the administration of the product.

   C: **Outcome: Enter the number which corresponds to the outcome in column C**

   1. **Resolved/ Recovered**: The AE was resolved

2. **Resolved with Sequelae**: The acute condition of the AE was resolved but the patient continues with complications
3. **Resolving/Ongoing**: The AE is getting better but still ongoing
4. **Fatal**: Patient death due to the AE or other conditions
5. **Unknown**: No information on the outcome of the AE. (i.e.: patient has transferred to another facility)

CANGENE

Cangene Corporation, a subsidiary of Emergent BioSolutions Inc.

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

BT-010
Case ID: Assigned by Cangene
(To be completed by Cangene Corporation)

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
		☐				- -	- -	☐
		☐				- -	- -	☐
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- **Concomitant Medications (Con Med):** Include those given as pre-treatment **and** in use at time of BAT Administration. Additional information can be written on back if needed.
- **Con Med/Corrective Treatment:** If possible provide the generic name of the drug
- **Indication:** If possible this should be a diagnosis, not a symptom
- **Dose:** The amount of the con med administered to the patient
- **Frequency (Doses per day):** The number of times the con med is administered to the patient.
- **Route:** Route of administration of the con med.
- **Ongoing:** Check only if no stop date for con med.