ECUSTEC SAE Form

TO BE COMPLETED FOR ANY SERIOUS ADVERSE EVENTS OCCURRING WITHIN THE PROTOCOL-DEFINED REPORTING PERIOD

Patient Identifier: ☐☐☐☐☐ Site Name:

Date of Birth: (mon/yyyy) Gender: ☐ Male ☐ Female

1. Report Type

☐ Initial Report ☐ Follow-Up Report* *If ticked; complete this section: SAE Ref No. ☐☐☐☐☐ / ☐☐

Has the new information changed the relatedness? ☐ Yes ☐ No PI Signature (dd/mon/yyyy)

2. Event Information

Diagnosis/Event Symptoms (CTCAE version 4.0, June 14th 2010)	Event Category (Enter Code from BCTU list)	Grade Refer to CTCAE document	Indicate which event became Serious (Tick one box only)
1.	☐☐☐☐☐☐	☐	☐
2.	☐☐☐☐☐☐	☐	☐
3.	☐☐☐☐☐☐	☐	☐
4.	☐☐☐☐☐☐	☐	☐

If event code = "other", please specify _____

Seriousness of event (please provide a response to each question)	**Yes***	**No**	**Details**
Death	☐	☐	⇨ *If Yes, date of death (dd/mon/yyyy) Cause of death: _____
Life threatening event	☐	☐	
In-patient hospitalisation or prolongation of existing hospitalisation	☐	☐	⇨ *If Yes, ☐ Initial ☐ Prolonged Date discharged (dd/mon/yyyy)
Persistent or significant disability/incapacity	☐	☐	
Congenital anomaly or birth defect	☐	☐	
Other pertinent medical reason for reporting?	☐	☐	⇨ *If Yes, please specify:_____

Date of onset	Date site became aware	Date became serious	Ongoing ? *If no, Date Resolved
(dd/mon/yyyy)	(dd/mon/yyyy)	(dd/mon/yyyy)	☐ Yes ☐ No* (dd/mon/yyyy)

Is the event related to any of the trial interventions? (tick only one option)

☐ unrelated
☐ unlikely to be related } "Unrelated"

☐ possibly related
☐ probably related
☐ definitely related } "Related"

Reason "unrelated": _____

Event listed in the protocol as an expected SAE? ☐ Yes ☐ No* ***If no, please send to BCTU within 24hrs with relevant reports**

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PAGE 2. TO BE COMPLETED FOR ANY SERIOUS ADVERSE EVENTS

Trial Number: ☐☐☐☐☐ Date of Birth: __ __ __ / __ __ __ __ (mon/yyyy)

3. Trial Intervention Summary (List details of all Trial Interventions being received when the SAE started)

Intervention (drug or device name)	Intervention Received Yes	Intervention Received No	Route of Administration 1 = oral 2 =IV 3 = sub-cutaneous	Dose (including units and frequency)	Intervention start date	Intervention ongoing Yes	Intervention ongoing No	Intervention Stopped Date (if relevant)	Causality Assessment (provide response for each Intervention) 1=unrelated 2=unlikely to be related 3=possibly related 4=probably related 5=definitely related
Trial Treatment	☐	☐	☐		(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)	☐
Antibiotic Name	☐	☐	☐		(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)	☐
ACWY Vaccine	☐	☐	☐		(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)	☐
Meningococcal B Vaccine	☐	☐	☐		(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)	☐

4. Concomitant Medication

Has the patient taken any other drugs which may interact with the intervention or influence the SAE?

☐ Yes* ☐ No

***If yes, please state which drugs may have interacted or influenced the SAE in the table below:**

Drug Name	Route of Administration 1 = oral, 2 =IV, 3= subcutaneous, 4=other	Dose (including units and frequency)	Start date	Ongoing? Yes	Ongoing? No	Stopped Date (if relevant)
	☐		(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)
	☐		(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)
	☐		(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)
	☐		(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)

5. Relevant Medical History

List any underlying **comorbidities or lab tests and investigations that are relevant**. (Where investigations or lab tests are appended please ensure patient identifiers replaced with trial number only)

DETAILS OF PERSON REPORTING

Signature of Person Reporting (you must have signed the site delegation log): _____	Name of Person Reporting: Position:
Date completed: (dd/monyyyy)	
Signature of Principal Investigator _____	Date PI Signed: (dd/mon/yyyy)

ECUSTEC SAE Form

TO BE COMPLETED BY THE CHIEF INVESTIGATOR OR NAMED DELEGATE

NOT TO BE COMPLETED BY TO THE PRINCIPAL INVESTIGATOR

Trial Number: ☐☐☐☐☐	Site Name:	
Date of Birth: (mon/yyyy)	Gender: ☐ Male	☐ Female
☐ Initial Report	☐ Follow-Up Report	SAE Ref No. ☐☐☐☐/☐☐

Causality Assessment (must be made with reference to the relevant safety information)

Intervention (drug or device name)	**Review of Causality Assessment** Related Yes	No	**Assessment of Expectedness** Expected Yes	No
Trial Treatment	☐	☐	☐	☐
Antibiotic Name	☐	☐	☐	☐
ACWY Vaccine	☐	☐	☐	☐
Meningococcal B Vaccine	☐	☐	☐	☐

If the evaluator's review disagrees with the PI's assessment, please state why you disagree with the PI assessment:

_____

_____

_____

Details of Person Evaluating Causality and Expectedness

Signature of Person Evaluating	Name of Evaluator:
Position: (CI or delegate)	Date of report:

FOR BCTU USE ONLY

Event Categorised as:	☐ SAE	☐ SAR	☐ SUSAR
Does this event require expedited reporting to;		Yes*	No
	A competent authority?	☐	☐
	An ethics committee?	☐	☐
	The Sponsor?	☐	☐
*If yes, state date sent to			Reporting Timeframe Met? Yes / No
	The competent authority	☐☐/☐☐☐/☐☐☐☐	☐ / ☐
	The ethics committee	☐☐/☐☐☐/☐☐☐☐	☐ / ☐
	The Sponsor	☐☐/☐☐☐/☐☐☐☐	☐ / ☐

Completed at BCTU by: OFFICE USE ONLY

Completed at BCTU by (name): _____

Signed: _____ Date: (dd/mon/yyyy)