ECUSTEC 60 Day Follow-up Form

TO BE COMPLETED FROM THE CASE NOTES AT 60 DAYS AFTER RANDOMISATION

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

Part A: Visit Details

Date of Visit: __ __ / __ __ __ / __ __ __ __ (dd/mon/yyyy)

Has the patient died? ☐ Yes ☐ No Has the patient/parent confirmed willingness to continue? ☐ Yes ☐ No	If the patient has died, or is unwilling to continue, please complete the **ECUSTEC Exit Form.**

Part B: Clinical Details

Height: ☐☐☐.☐ cm	Weight: ☐☐☐.☐ kg
Blood pressure (average of 3 recordings): ☐☐☐/☐☐☐ mmHg	

Part C: Quality of Life Questionnaires (refer to Appendix 3 of protocol for age suitable version)

Have the standardised, patient/parent completed, questionnaires been completed at this assessment visit?

Form	CHU-9D	Peds-QL
	☐ Yes ☐ No	☐ Yes ☐ No

Part D: Bloods and Biochemistry (at visit) Note - If patient is still in hospital, and day 60 bloods/biochemistry not taken, then day 56 values can be used.

Parameter	Reading
Albumin/creatinine ratio (from early morning urine)	☐☐☐.☐ mg/mmol
eGFR	☐☐☐.☐ ml/min/1.73m^2
Serum creatinine	☐☐☐.☐ µmol/l

Part E: Signs and Symptoms for Meningococcal Disease and Septicaemia (at visit)

Does the patient have signs or symptoms for meningococcal disease and/or septicaemia? ☐ Yes* ☐ No
*If yes, urgent medical treatment in accordance with local clinical procedures should be started immediately.

Are parents/patient/guardian in possession of the ECUSTEC Meningitis Warning Card and ECUSTEC Patient Study Card?
☐ Yes ☐ No

Part F: Protocol-mandated Antibiotic Therapy

Has trial-mandated antibiotic cover continued? (penicillin, erythromycin)	☐ Yes* ☐ No
If yes, which trial-mandated antibiotic has commenced? ☐ Penicillin ☐ Erythromycin ☐ Other	
*If other specify _____	Dose ☐☐☐mg Frequency: _____

Other Antibiotics (as supportive treatment received between either discharge from initial admission, or Day 30 (if discharged before day 30), and Day 60.)

Were additional antibiotics given? ☐ Yes ☐ No	Specify Antibiotic given _____
Start Date: (dd/mon/yyyy)	Stop Date: (dd/mon/yyyy)

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Part G: Infection Status for Grade ≥ 3 (since discharge or Day 30, whichever is most recent.)

Has the patient had a severe wound infection? *If yes, how many? ☐☐	☐ Yes*	☐ No
Has the patient had a severe vascular catheter infection? *If yes, how many? ☐☐	☐ Yes*	☐ No
Has the patient had a severe episode of peritonitis? *If yes, how many? ☐☐	☐ Yes*	☐ No
Has the patient had any other severe infections? *If yes to "other", please state: _____	☐ Yes*	☐ No

If the patient has experienced an event which:

- ***Is fatal***
- ***Or life-threatening***
- ***Caused either admission to hospital or prolongation of a hospital stay***
- ***Resulted in persistent or significant disability or incapacity***
- ***Resulted in a congenital anomaly/birth defect***

Please complete the ECUSTEC Serious Adverse Event (SAE) Form.
For further details please refer to Section 10.3, SAE Definition and Reporting, of the ECUSTEC Protocol.

Part H: Targeted Concomitant Medications (since discharge or Day 30, whichever is most recent.)	Yes	No
Anti-hypertensive medication (except ACE inhibitor or Angiotensin Receptor Blocker)	☐	☐
ACE inhibitor or Angiotensin Receptor Blocker	☐	☐
Folic Acid	☐	☐
Alfacaclidol	☐	☐
Calcium supplement (except Calcium carbonate or acetate)	☐	☐
Phosphate binder (eg calcium carbonate, calcium acetate, sevelemar)	☐	☐

Part I:Hospital and Healthcare Professional (HCP) Contacts (Do NOT include visits for repeat prescriptions)

Has the patient been seen in the following clinics or departments since the last protocol-mandated visit?
(This includes visits to the family home by hospital based nurses)

Any GP or other HCP	☐ Yes*	☐ No	*If yes please complete: **ECUSTEC Healthcare Contact Form**
A&E department	☐ Yes*	☐ No	*If yes please complete: **ECUSTEC Healthcare Contact Form**
Hospital outpatient department	☐ Yes*	☐ No	*If yes please complete: **ECUSTEC Healthcare Contact Form**
Admitted to any hospital	☐ Yes**	☐ No	

**If yes please complete:

- **ECUSTEC Healthcare Contact Form**
- **An SAE Form** for any admissions
  - within 90 days of initial meningococcal vaccination or prophylactic antibiotics
  - That are NOT for routine treatment or monitoring of the studied indication
  - That are NOT solely to provide dialysis access

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Part J (a): Plasma Exchange and Plasma Infusions (since discharge or Day 30, whichever is most recent.)

Did the patient have a **plasma** infusion?	☐ Yes* ☐ No
*If yes, how many infusions? ☐☐	
Infusion 1 volume ☐☐☐ ml	Start Date: (dd/mon/yyyy) Time of Treatment ☐h☐h:☐m☐m (24 hour clock)
Infusion 2 volume ☐☐☐ ml	Start Date: (dd/mon/yyyy) Time of Treatment ☐h☐h:☐m☐m (24 hour clock)
Infusion 3 volume ☐☐☐ ml	Start Date: (dd/mon/yyyy) Time of Treatment ☐h☐h:☐m☐m (24 hour clock)

Did the patient have a **plasma exchange** (PE)?	☐ Yes* ☐ No
*If yes, how many exchanges? ☐☐	
1st Plasma Exchange	Start Date: (dd/mon/yyyy) Stop Date: (dd/mon/yyyy)
2nd Plasma Exchange	Start Date: (dd/mon/yyyy) Stop Date: (dd/mon/yyyy)
3rd Plasma Exchange	Start Date: (dd/mon/yyyy) Stop Date: (dd/mon/yyyy)

Part J (b): Red Blood Cell Transfusions (since discharge or Day 30, whichever is most recent.)

Did the patient have a **red blood cell** transfusion?	☐ Yes* ☐ No
*If yes, how many transfusions? ☐☐	
Transfusion 1 volume ☐☐☐ ml/kg	Date: (dd/mon/yyyy) Time of Treatment ☐h☐h:☐m☐m (24 hour clock)
Transfusion 2 volume ☐☐☐ ml/kg	Date: (dd/mon/yyyy) Time of Treatment ☐h☐h:☐m☐m (24 hour clock)
Transfusion 3 volume ☐☐☐ ml/kg	Date: (dd/mon/yyyy) Time of Treatment ☐h☐h:☐m☐m (24 hour clock)

Part K: Renal Function (since discharge or Day 30, whichever is most recent.)

Relevant Event Name	Event Recorded Yes*	Event Recorded No	*If yes: Date on which decision made to start RRT	Start Date	Stop Date (if relevant)	Dialysis Dependent at this time point? Yes	Dialysis Dependent at this time point? No
Dialysis/RRT	☐	☐	(dd/mon/yyyy)	(dd/mon/yyyy)	(dd/mon/yyyy)	☐	☐

Type of RRT (tick all that apply): ☐ Haemodialysis ☐ Peritoneal ☐ CRRT

If RRT stopped, please state the reason why below:

Access failure	☐ **Yes** ☐ **No**	
No longer indicated	☐ **Yes** ☐ **No**	
Other	☐ **Yes*** ☐ **No**	

*If reason RRT stopped is other, state reason: _____

Number of RRT access procedures required: ☐☐

Lowest eGFR :

Lowest eGFR reported since randomisation: Date lowest eGFR recorded: (dd/mon/yyyy) Value: ☐☐☐.☐ ml/min/1.73m^2

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

Part L: CNS Investigations Summary (between discharge and Day 60.)

Were there any CNS investigations between discharge and Day 60?	☐ Yes*	☐ No
*If yes, please enter each event below separately:		

Relevant Investigation Name	Investigation 1 Recorded	Investigation 2 Recorded	Investigation 3 Recorded	Investigation 4 Recorded
EEG performed	☐ Yes* ☐ No	☐ Yes* ☐ No	☐ Yes* ☐ No	☐ Yes* ☐ No
*If yes, give date	(dd/mon/yyyy)	(dd/mon/yyyy)	(dd/mon/yyyy)	(dd/mon/yyyy)
*If yes, please select **one** of the options below for each event recorded:				
No abnormal findings	☐	☐	☐	☐
Focal abnormality in one hemisphere	☐	☐	☐	☐
Multi-focal abnormalities confined to one hemisphere	☐	☐	☐	☐
Multi-focal abnormalities involving both hemispheres	☐	☐	☐	☐
Generalised abnormality with no particular focus	☐	☐	☐	☐
Cerebral MRI performed	☐ Yes* ☐ No	☐ Yes* ☐ No	☐ Yes* ☐ No	☐ Yes* ☐ No
*If yes, give date	(dd/mon/yyyy)	(dd/mon/yyyy)	(dd/mon/yyyy)	(dd/mon/yyyy)
*If yes, please select **one** of the options below for each event recorded:				
No abnormal findings	☐	☐	☐	☐
Focal abnormality in one hemisphere	☐	☐	☐	☐
Multi-focal abnormalities confined to one hemisphere (+/- ipsilateral cerebellum):	☐	☐	☐	☐
Multi-focal abnormalities involving both hemispheres (+/- contralateral cerebellum)	☐	☐	☐	☐

Part M: Neurological Findings (between discharge and Day 60.)

Completed by/with paediatric neurologist

	Yes	No
Any Obvious CNS involvement?	☐ *	☐
(*If yes, complete questions below)		
Altered consciousness (Agitation, irritability, hallucinations, confusion, excessive drowsiness)	☐	☐
Single seizure	☐	☐
Two or more seizures 24 hrs apart	☐	☐
Transient focal neurological defect (>24 hours but <1 week)	☐	☐
Persistent focal neurological defect (present at day 60 and persistent for more than 1 week)	☐	☐
Persistent global (≥ 2 brain functions - vision/hearing/cognitive/motor/sensory/memory) neurological defect at day 60	☐	☐

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

Part N: Pancreatic Findings (between discharge and Day 60.)

Event	Event Recorded
Any Clinical or biochemical evidence of Pancreatitis?	☐ Yes* ☐ No
(*If yes, complete questions below)	
Raised amylase and/or lipase without clinical symptoms/signs	☐ Yes ☐ No
Hyperglycaemia without insulin requirement	☐ Yes ☐ No
Pancreatitis with sequelae eg. Laparotomy, parenteral nutrition due to pancreatitis, insulin required	☐ Yes ☐ No
Chronic sequelae of pancreatitis at day 60 (parenteral nutrition due to pancreatitis, insulin, other)	☐ Yes ☐ No

Part O: Gastrointestinal Surgery (between discharge and Day 60.)

Event	Event recorded? Yes*	No	Procedure date	
Abdominal surgery (not related to catheter insertion)	☐	☐		
*If yes to abdominal surgery please select which of the below were required/detected:				
Laparoscopy/laparotomy	☐	☐	(dd/mon/yyyy)	
Intestinal perforation AND/OR bowel resection	☐	☐	(dd/mon/yyyy)	
Stoma formation	☐	☐	(dd/mon/yyyy)	

Part P: Cardiac Findings (between discharge and Day 60.)

Event	Event Recorded? Yes	No
Any Cardiac Involvement (normal CVS examination—except hypertension/volume overload)	☐ *	☐
(*If yes, complete questions below)		
Cardiac failure confirmed by ECHO (impaired systolic ventricular function or chamber enlargement or valve regurgitation)	☐	☐
Cardiac failure confirmed by ECHO with dilated cardiomyopathy	☐	☐
Myocardial infarction (on standard ECG +/- troponin +/- ECHO evidence)	☐	☐

Part Q: Form Completion

Completed by (name): _____

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

PI Name: _____

PI Confirmation Signature: _____ Date Completed: (dd/mon/yyyy)