ECUSTEC 30 Day Follow-up Form

TO BE COMPLETED FROM THE CASE NOTES AT 30 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 30 bloods/biochemistry not taken, then day 28 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 randomisation (if still in hospital) and Day 30.)

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: Patient Discharge

Has the patient been discharged from hospital prior to the Day 30 assessment? ☐Yes ☐No*	*If no please go to Part M (page 4)

Part H - Part L only to be completed if the patient has been discharged from hospital prior to the day 30 assessment

Part H: Infection Status for Grade ≥ 3 (between discharge from initial admission and Day 30.)

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 I: Targeted Concomitant Medications (between discharge from initial admission and Day 30.)	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 J: 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

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

Part K (a): Plasma Exchange and Plasma Infusions (between discharge from initial admission and Day 30.)

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 K (b): Red Blood Cell Transfusions (between discharge from initial admission and Day 30.)

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)
Transfusion 4 volume ☐☐☐ ml/kg	Date: (dd/mon/yyyy) Time of Treatment ☐h☐h:☐m☐m (24 hour clock)
Transfusion 5 volume ☐☐☐ ml/kg	Date: (dd/mon/yyyy) Time of Treatment ☐h☐h:☐m☐m (24 hour clock)
Transfusion 6 volume ☐☐☐ ml/kg	Date: (dd/mon/yyyy) Time of Treatment ☐h☐h:☐m☐m (24 hour clock)

Part L: Renal Function (between discharge from initial admission and Day 30.)

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: ☐

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

Part M: Sample Tracking (Please ensure the sample log in the site file is completed)

Optional/Not Optional	Sample Type	Consent optional samples? Yes	Consent optional samples? No	Day 30 Sample taken? Yes	Day 30 Sample taken? No
Not optional	Stool*			☐	☐
*If no stool sample was taken, were stool collection tubes and postal packaging provided?				☐	☐
Optional	Blood (EDTA)	☐	☐	☐	☐
Optional	Blood (Lithium heparin)	☐	☐	☐	☐
Optional	Urine	☐	☐	☐	☐
Notes/problems with sample preparation, if any. Please include a reason for not providing a stool collection kit if one was not provided and no stool sample was taken: (Please specify which sample)					

Part N: Form Completion

Completed by (name): _____

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

PI Name: _____

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