ECUSTEC Initial Admission for Trial Treatment Form

TO BE COMPLETED AT DISCHARGE FROM INITIAL HOSPITAL ADMISSION FOR TRIAL TREATMENT OR UPTO DAY 56, WHICHEVER IS SOONEST

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

Part A: Assessment Details

Date of Admission: (dd/mon/yyyy) Date of Discharge: (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.**

Location of Patient During Admission (put "0" if patient did not stay on the relevant ward type, record stay episodes on separate lines)

General Ward (Stay 1)	Days on ward ☐☐	Start Date: (dd/mon/yyyy)	Stop Date: (dd/mon/yyyy)
General Ward (Stay 2)	Days on ward ☐☐	Start Date: (dd/mon/yyyy)	Stop Date: (dd/mon/yyyy)
PICU (Stay 1)	Days on ward ☐☐	Start Date: (dd/mon/yyyy)	Stop Date: (dd/mon/yyyy)
PICU (Stay 2)	Days on ward ☐☐	Start Date: (dd/mon/yyyy)	Stop Date: (dd/mon/yyyy)
HDU (Stay 1)	Days on ward ☐☐	Start Date: (dd/mon/yyyy)	Stop Date: (dd/mon/yyyy)
HDU (Stay 2)	Days on ward ☐☐	Start Date: (dd/mon/yyyy)	Stop Date: (dd/mon/yyyy)
Theatre Visit	No. of Visits ☐☐	Procedures: _____	

Part B: Vaccinations

	Yes*	No	*If yes, Date
Has the patient received conjugate meningococcal ACWY vaccine (Nimenrix or Menveo)?	☐	☐	(dd/mon/yyyy)
Has the patient received Meningococcal B vaccine (Bexsero™) as part of the **UK immunisation programme**?	☐	☐	(dd/mon/yyyy)
Has the patient received Meningococcal B vaccine (Bexsero™) as part of the **ECUSTEC trial**?	☐	☐	(dd/mon/yyyy)

Part C: Signs and Symptoms for Meningococcal Disease and Septicaemia

Has the patient had signs or symptoms for meningococcal disease and/or septicaemia? ☐ Yes ☐ No

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

Part D: Protocol-mandated Therapy

Has trial-mandated antibiotic cover for 2 weeks post-discharge been supplied? ☐ Yes ☐ No ☐ Not Applicable

Has antibiotic cover by the GP been confirmed, in line with the ECUSTEC Initial GP Letter? ☐ Yes ☐ No ☐ Not Applicable

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Part E: Infection Status for Grade ≥ 3 (During this admission.)

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.

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Part F: Laboratory Readings

Bloods and Biochemistry (To be completed from the case notes. Please state whether there were abnormal readings between baseline (not including values reported on the baseline form) and discharge/day 56, whichever is soonest for the parameters below.)

Parameter	Raised Reading Yes*	No	*If raised, peak reading	Date of Peak	Ongoing Yes	No	Date returned to normal range (if applicable)
White blood cell count	☐	☐	☐☐.☐ 10^9/L	(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)
Urea	☐	☐	☐☐.☐ mmol/L	(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)
				Date of Onset of abnormal range			Date of Resolution
Lactose Dehydrogenase (LDH)	☐	☐	☐☐☐☐ U/L	(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)
C-reactive Protein	☐	☐	☐☐☐☐ mg/L	(dd/mon/yyyy)	☐	☐	(dd/mon/yyyy)

Regular Laboratory Readings (Please complete daily laboratory readings for neutrophil cell count, platelets and sodium, up until discharge or day 14, which ever is soonest. If still in hospital after day 14 and resolution has not occurred, weekly readings should be collected.)

Regular Neutrophil Cell Count (Day 1 is prior to trial drug administration and is recorded on the Baseline Form)

Day	Recorded? Yes	No	Date of Reading	Neutrophil Cell Count	Outside normal range? Yes	No
2	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
3	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
4	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
5	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
6	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
7	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
8	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
9	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
10	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
11	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
12	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
13	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
14	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
21	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
28	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
35	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
42	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
49	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐
56	☐	☐	(dd/mon/yyyy)	☐☐.☐ 10^9/L	☐	☐

Has the neutropenia been resolved? ☐ Yes* ☐ No ☐ Not Applicable

*If yes, provide the date of resolution: (dd/mon/yyyy)

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

Regular Platelet Readings (Day 1 is prior to trial drug administration and is recorded on the Baseline Form)

Day	Recorded? Yes	Recorded? No	Date of Reading	Platelet Count	Had the patient had a platelet transfusion on day of reading? Yes	Had the patient had a platelet transfusion on day of reading? No
2	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐
3	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐
4	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐
5	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐
6	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐
7	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐
8	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐
9	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐
10	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐
11	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐
12	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐
13	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐
14	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐

Where the patient remains in hospital after day 14 and weekly platelet readings are being recorded, please state the date on which any transfusion occurred in the previous week

Day	Recorded Yes	Recorded No	Date of Reading	Platelet count	Has the patient had a platelet transfusion since the previous recorded reading? Yes*	Has the patient had a platelet transfusion since the previous recorded reading? No	*If yes, Date of Transfusion
21	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐	(dd/mon/yyyy)
28	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐	(dd/mon/yyyy)
35	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐	(dd/mon/yyyy)
42	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐	(dd/mon/yyyy)
49	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐	(dd/mon/yyyy)
56	☐	☐	(dd/mon/yyyy)	☐☐☐ 10^9/L	☐	☐	(dd/mon/yyyy)

Has the thrombocytopenia been resolved? ☐ Yes* ☐ No

*If yes, provide the date of resolution: (dd/mon/yyyy)

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

Regular Sodium Readings (Day 1 is prior to trial drug administration and is recorded on the Baseline Form)

Day	Recorded? Yes	Recorded? No	Date of Reading	Sodium Reading	Outside normal range? Yes	Outside normal range? No
2	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
3	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
4	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
5	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
6	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
7	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
8	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
9	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
10	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
11	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
12	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
13	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
14	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
21	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
28	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
35	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
42	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
49	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐
56	☐	☐	(dd/mon/yyyy)	☐☐☐ mmol/L	☐	☐

Has any sodium derangement been resolved? ☐ Yes* ☐ No ☐ Not Applicable

*If yes, provide the date of resolution: (dd/mon/yyyy)

Part G: Targeted Concomitant Medications (between randomisation and discharge/day 56, whichever is soonest.)	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)	☐	☐

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Part H(a): Plasma Exchange and Plasma Infusions (received since 2nd dose of trial treatment and up to discharge/day 56, whichever is soonest.)

Note - patients should NOT receive plasma exchange

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 H(b): Red Blood Cell Transfusions (received since Randomisation and up to discharge/day 56, whichever is soonest.)

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)

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

Part I (a): Renal Function (between randomisation and discharge/day 56, whichever is soonest.)

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 Discharge? Yes	Dialysis Dependent at Discharge? No
Dialysis/RRT	☐	☐	(dd/mon/yyyy)	(dd/mon/yyyy)	(dd/mon/yyyy)	☐	☐

*If yes, 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: ☐

Part I (b): If answered 'no' to Dialysis/RRT, please provide the following values (between randomisation and discharge/day 56, whichever is soonest.)

Lowest eGFR ☐☐☐.☐ ml/min/1.73m^2	(dd/mon/yyyy)	
Highest serum creatinine ☐☐☐.☐ µmol/l	dd/mon/yyyy)	
Serum creatinine at discharge/day 56, whichever is soonest ☐☐☐.☐ µmol/l	dd/mon/yyyy)	

Part I (c): Oligoanuria (between randomisation and discharge/day 56, whichever is soonest.)

Oligoanuria post randomisation (defined as <0.5ml/kg/hr for 12 hours)	☐ Yes ☐ No	Start Date:(dd/mon/yyyy) Stop Date: (dd/mon/yyyy)

Part J: Sample Tracking (during in-patient stay. Please complete the samples log in the site file).

Optional/Not Optional	Sample	Consent optional samples?	Day 2 Sample taken?	Day 4 Sample taken?	Day 6 Sample taken?	Day 8 Sample taken?
Optional	Blood (Neutrophils)	☐ Yes ☐ No	Date sample taken: __ __ /__ __ __ / __ __ __ __ (dd/mon/yyyy)			
Not optional	Blood EDTA—genetics		Date sample taken: __ __ /__ __ __ / __ __ __ __ (dd/mon/yyyy)			
Optional	Blood (EDTA)	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Optional	Blood (co-culture')	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Optional	Urine	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
Notes/problems with sample preparation, if any: (Please specify which sample)						

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

Part K: CNS Investigations Summary

Were there any CNS investigations - since randomisation?	☐ Yes*	☐ No
*If yes, please enter each investigation 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)	☐	☐	☐	☐

Note: If neurological abnormalities are detected, book 60 day neurological assessments as per protocol

Part L: Neurological Findings (since randomisation)	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)	☐	☐

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Part M: Pancreatic Findings (since randomisation)

Event	Event Recorded
Was parenteral nutrition given?	☐ Yes* ☐ No
*If yes, why was parenteral nutrition given? ☐ Pancreatitis ☐ Other	
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 (non-fasting glucose ≥ 11mmol/l, fasting glucose ≥7mmol/l) without insulin requirement	☐ Yes ☐ No
Pancreatitis with sequelae eg. Laparotomy, parenteral nutrition due to pancreatitis, insulin required	☐ Yes ☐ No

Part N: Gastrointestinal Surgery (since randomisation)

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 O: Cardiac Findings (since randomisation)

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 P: Form Completion

Completed by (name): _____

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

PI Name: _____

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