ECUSTEC 26 & 52 Week Follow-up Form

TO BE COMPLETED FROM THE CASE NOTES AT 26 AND 52 WEEKS AFTER RANDOMISATION

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

Part A: Visit Details

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

Assessment point (please tick): ☐ 26 weeks ☐ 52 weeks

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?

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

Part D: Bloods and Biochemistry (at visit)

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

Part E: Infection Status for Grade ≥ 3 (between day 60 and 26 weeks OR between 26 and 52 week assessments.)

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 "other" infection, please state: _____	☐ Yes*	☐ No

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Part F: Targeted Concomitant Medications (between day 60 and 26 weeks OR between 26 and 52 week assessments.)	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 G: 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 Heathcare Contact Form**
A&E department	☐ Yes*	☐ No	*If yes please complete: **ECUSTEC Heathcare 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

Part H: Renal Function (between day 60 and 26 weeks OR between 26 and 52 week assessments.)

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

At 52 weeks only: Does the patient have chronic kidney disease? ☐ Yes ☐ No

Note - the presence of hypertension [average of 3 readings by manual method using centile charts for age/sex/height], albuminuria [urine albumin-creatinine ratio >2.5mg/mmol on early morning urine] or estimated glomerular filtration rate (eGFR) <90ml/min/1.73m^2 at 52 weeks). Presence of any of these will constitute CKD at 52 weeks

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Part I: Sample Tracking (At 52 Weeks only.) **Please ensure the sample log in the site file is completed.**

Optional/Not Optional	Sample Type	Consent optional samples? Yes No	Week 52 Sample taken? Yes No
Not optional	Blood (serum)		☐ ☐
Notes/problems with sample preparation, if any: (Please specify which sample)			

Part J: Form Completion

Completed by (name):

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

PI Name: _____

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