ECUSTEC Day 8 Certificate of Vaccination

Once complete, please forward a copy of the certificate to the local trial site pharmacy in order for trial site pharmacist to dispense second dose of Ecu/placebo.

Once complete, please forward a copy of the certificate to the ECUSTEC Trials Office no later than 48 hours after the 2nd dose of Ecu/placebo.

ECUSTEC Trials Office:

Fax No.: 0121 415 9135 or email (ECUSTEC@Trials.bham.ac.uk)

Date: Name of prescriber:

Clinical trial site name:

ECUSTEC trial number: ☐☐☐☐☐

Is the patient platelet count ≥50x10^9/l? ☐ Yes ☐ No

I confirm that:

☐ Antibiotic prophylaxis will continue for 8 weeks (mandatory)

☐ The patient/parent/guardian has been reminded about the "Participant Safety Card" and relevant educational materials

Vaccination

ACWY vaccine – tick one

☐ The patient has received a conjugate ACWY meningococcal vaccination

☐ The patient will receive a conjugate ACWY meningococcal vaccination once platelet count ≥50x10^9/l (and before discharge from the trial site)*

☐ The patient will receive a conjugate ACWY meningococcal vaccination once anticoagulation has been stopped for 24 hours and is not anticipated to recommence**

Bexsero vaccine – tick one

☐ The patient received Meningococcal B vaccine (Bexsero™) as part of the UK (or equivalent) immunisation programme

If the patient received Meningococcal B vaccine (Bexsero™) as part of the UK (or equivalent) immunisation programme has confirmation (e.g. red book documentation or written confirmation by GP practice team) been received? ☐ Yes ☐ No

☐ The patient received Meningococcal B vaccine (Bexsero™) as part of the ECUSTEC trial

☐ The patient will receive Bexsero vaccination once platelet count ≥50x10^9/l (and before discharge from the trial site)*

☐ The patient will receive Bexsero vaccination once anticoagulation has been stopped for 24 hours and is not anticipated to recommence**

Vaccinations according to the routine UK immunisation schedule

☐ The patient received Haemophilus influenza vaccination as part of the UK immunisation programme

If the patient received Haemophilus influenza as part of the UK immunisation programme has confirmation (e.g. red book documentation or written confirmation by GP practice team) been received? ☐ Yes ☐ No

☐ The patient received pneumococcal infection vaccination as part of the UK immunisation programme

If the patient received pneumococcal infection vaccination as part of the UK immunisation programme has confirmation (e.g. red book documentation or written confirmation by GP practice team) been received? ☐ Yes ☐ No

Signed:

Date:

Name:

* If meningococcal vaccination is deferred because of platelet count <$50x10^9$/l, vaccination should be administered as soon as the platelet count rises to ≥$50x10^9$/l.

**If meningococcal vaccination is deferred because patient is receiving systemic anticoagulation, vaccination will be deferred until anticoagulation has stopped for 24 hours and is not anticipated to recommence.

The second dose of IMP will not be released unless the local investigator confirms that both vaccinations have been given (or Bexsero confirmed as not required), and antibiotic prophylaxis is continuing, EXCEPT in the event that the platelet count remains <$50x10^9$/l when the investigator will agree to proceed to vaccination as soon as the platelet count is ≥$50x10^9$/l, or in the event systemic anticoagulation is occurring when the investigator will agree to proceed to vaccination as soon as systemic anticoagulation has been stopped for 24 hours and is not anticipated to recommence. In this situation vaccination MUST be given prior to discharge from hospital and Alexion, the Trial Office and local trial site pharmacy notified using the ECUSTEC Pre-discharge Certificate of Vaccination. If the platelet count has not risen to ≥$50x10^9$/l by discharge please contact the CI for advice.

Original in Site File, copy in the medical notes, copy to Birmingham Clinical Trials Unit and copy to local pharmacy.