# ECUSTEC Day 1 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 first dose of Ecu/placebo.**

**Once complete, please forward a copy of the certificate to Alexion and to the ECUSTEC Trials Office no later than 48 hours after the 1st dose of Ecu/placebo.**

**Alexion:**

**Fax No.: 0800 633 5145 or email (CustomerOperationsUK@alexion.com)**

**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: ☐☐☐☐☐

I confirm that:

☐ This patient/parent/guardian has received information on the ECUSTEC trial and given informed consent to participate (mandatory)

☐ I have delivered to the patient/parent/guardian the "Participant Safety Card" and relevant educational materials (mandatory)

☐ The patient has received his/her first dose of prophylactic antibiotics (mandatory)

☐ Antibiotic prophylaxis will continue for 8 weeks (mandatory)

☐ Patient/parent/guardian reported that vaccinations are up to date according to the routine UK immunisation schedule.

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 ≥50x$10^9$/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 has received Bexsero vaccination either as part of the UK (or equivalent) Immunisation programme or as part of the ECUSTEC trial

☐ The patient will receive Bexsero vaccination once platelet count ≥50x$10^9$/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 **

Signed:

Date:

Name:

* If meningococcal vaccination is deferred because of platelet count <50x$10^9$/l, vaccination should be administered as soon as the platelet count rises to ≥50x$10^9$/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 <50x$10^9$/l when the investigator will agree to proceed to vaccination as soon as the platelet count is ≥50x$10^9$/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. Alexion, the Trial Office and local trial site pharmacy MUST also be notified using the ECUSTEC Pre-discharge Certificate of Vaccination. If the platelet count has not risen to ≥50x$10^9$/l by discharge please contact the CI for advice.

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