

End of Trial Form (Month 15) / Early Withdrawal

1. Did the patient complete the Trial to Month 15?

YES

A.1. Has the Research Nurse/GP spoken to the patient to discuss their individual results?

(i) YES

(ia) Date seen: : _____ dd/mm/yyyy

(ii) NO – (please arrange an appointment).

(iia) Date of appointment: _____ dd/mm/yyyy

A.2. Has the patient seen his/her GP since end of Treatment Period 6?

(i) YES

(ii) NO (please remind the patient to book an appointment)

(iia) Date reminder done: _____ dd/mm/yyyy

A.3. Has the patient been given a statin prescription in the 12 weeks since Treatment Period 6 ended?

(i) YES

(ia) Name of Statin: _____

(ib) Dose of statin: _____

(ic) Date of issue of prescription: _____

(ii) NO

(iia) If no statin has been prescribed, does the patient intend on re-starting long term statin therapy?
YES/NO/Don't know

A.4. Has the patient found their own trial results helpful to reach the decision as to whether to continue statin use?
YES/NO

NO

B.1. Please tick reason why the patient did not complete the trial:

☐ Lost to follow-up

☐ Early withdrawal

☐ Death

B.2. Lost to follow-up:

Date of last contact with patient? _____

Dd/mm/yyyy

B.3. If Early withdrawal, give reason:

a. withdrawal of informed consent

b. intolerable muscle symptoms*

c. clinical concern*

d. other*

*: please enter details here: _____

B.4. Has the patient contacted their GP to discuss reason for withdrawal?

(i) YES

(ia) Date seen: : _____ dd/mm/yyyy

(ii) NO – (advise patient to contact GP).

B.5. Has the Research Nurse/GP spoken to the patient to discuss their individual results?

(i) YES

(ia) Date seen: : _____ dd/mm/yyyy

(ii) NO – (please arrange an appointment).

(iia) Date of appointment: _____ dd/mm/yyyy

B.6. Death

B.6.a. Date of death: _____ dd/mm/yyyy

B.6.b Cause of death (either autopsy report or clinical judgement if autopsy not available):

B.6.c. Date SAE form completed: _____ dd/mm/yyyy
(if applicable)

C.1. This form was completed by: _____ Date: dd/mm/yyyy