VITATOPS Major Events Form *(page 1)*

Please use a black pen & BLOCK PRINT IN CAPITALS

Patient initials: _____ Signature of randomising Dr/RN:_____ VITATOPS number: _____

PRIMARY & SECONDARY OUTCOME EVENTS *(For serious adverse events see below)*
Has the patient had an outcome event or died ? Yes (1) No (2) If Yes, date _____/_____/_____
dd mm yyyy

Was the event fatal? Yes (1) No (2)

Nature of the outcome event or death *(please circle one or more):*

Primary:

(1) Ischaemic stroke of the brain
Please circle likely cause:
(a) large artery disease
(b) small vessel disease
(c) embolism from the heart
(d) of unknown or uncertain cause

(2) Ischaemic stroke of the eye
Please circle likely cause:
(a) large artery disease
(b) small vessel disease
(c) embolism from the heart
(d) of unknown or uncertain cause

(3) Haemorrhagic stroke - intracerebral haemorrhage
(4) Haemorrhagic stroke - subarachnoid haemorrhage
(5) Stroke of unknown pathological type
(6) Procedure-related stroke
(7) Myocardial infarction
(8) Other vascular death (eg pulmonary embolus, ruptured aortic aneurysm, heart failure, sudden presumed cardiac death) *Please specify* _____

Secondary:

(9) Non vascular death (*please specify cause of death)* _____
(10) TIA of brain or eye
(11) Revascularization procedures (eg percutaneous transluminal coronary angioplasty [PTCA with or without stent placement], coronary artery bypass surgery, carotid endarterectomy, percutaneous transluminal carotid angioplasty with or without stent replacement, peripheral arterial bypass surgery or any therapeutic intervention for critical leg ischaemia [including toe & leg amputation for PAD]).
Please specify_____
(12) Unstable angina
(13) Pulmonary embolus (non-fatal)
(14) Deep vein thrombosis
(15) Osteoporotic fracture *(Please Circle)* (a) probable or (b) definite
Please Circle Site of Fracture:
(i) neck of femur (ii) distal radius
(iii) thoracic spine (iv) other: please specify _____
(16) Dementia
(17) Depression

SERIOUS ADVERSE EVENTS
(Please notify the trial office immediately on +61 8 9224 7004 of all suspected serious adverse events)
Has the patient experienced a serious adverse event? Yes (1) No (2) If Yes, date _____/_____/_____
dd mm yyyy

Nature of the event: (*please specify)* _____
_____

ICD-10 Category (1-21)_____

Relationship of the serious adverse event to study medication *(please circle):*

(1) Not related
(2) Possibly related
(3) Probably related
(4) Definitely related

Other comments:_____

_____

Please FAX this form now to: VITATOPS Trial coordinator Fax: 0800 291 523
Please complete the accompanying page

VITATOPS Major Events Form *(page 2)*

Please use a black pen & BLOCK PRINT IN CAPITALS

Patient initials: _____ Signature of randomising Dr/RN:_____ VITATOPS number: _____

Date of Primary Event: ____/____/_____
dd mm yyyy

Please provide the details of any adverse event, primary & secondary outcome events or death below

Date of Onset:_____/____/_____
dd mm yyyy

Description of Onset:_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

Duration: _____

_____

Did patient stop the trial medication at all during this event? Yes (1) No (2)
If yes, specify date patient ceased and recommenced study tablets.

_____

Details:_____

_____

_____

_____

_____

_____

_____

Any precipitating factors:_____

_____

_____

_____

_____

Pathology *(Please FAX a copy of any relevant investigations):*

_____

_____

If the event was a stroke was it a disabling stroke (Rankin ≥ 3) or not (Rankin < 3) on the first day of the stroke?

_____

_____

Please FAX this form now with a copy of all relevant investigations to:

VITATOPS Trial coordinator Fax: 0800 291 523