6-Week Clinic Visit

What to do at the 6-Week Visit:

- Assess medication adherence
- Determine if any events have occurred and complete event forms as necessary
- Perform local safety blood tests
- Measure blood pressure and heart rate
- Reinforce lifestyle and study medication adherence
- Schedule next Interim call (3 Months ± 14 days) and 6-Month (± 14 days) visit

Forms to be submitted within 3 days of Visit

Visit Forms:

- 6-Week Visit Forms: 6W 1 - 6W 4

Shuttle Forms:

- **Fax:** Event Supporting Documentation Shuttle Form*
- **Fax:** Local Laboratory Shuttle Form

Event Forms:

- Event Form(s), as applicable*

*Complete only if an event has occurred

6 WEEK VISIT DATE

If, for some reason, the participant cannot return to the clinic within the visit window, it is preferable to have a late visit rather than miss the visit altogether. If an office visit is not possible, please contact the participant by telephone or other means. **Remember, even if the participant is not taking study drugs, they should be followed until study end.**

VISIT ADHERENCE

If participant did not return to the clinicor provide information, check only ONE appropriate box to indicate the reason why this visit was not completed.

1) Refused: Ask the participant if he/she will agree to be followed by a telephone call - whether or not they discontinue use of study medication. Every attempt should be made to maintain contact in order to record the primary and secondary outcomes. If the participant refuses regular telephone calls, request if one annual call can be made. If this is refused, request one final telephone contact just before study end.
2) Unable to contact: Please remember to use all possible contact options before checking this box, i.e., family physician, third party contact person/relative, medical records or other resources (refer to Contact Details Form). Please make sure some of the telephone calls are in the evening or on the weekends.

A. MEDICATION ADHERENCE

1. a) Please ask the participant if they are taking their **Polycap** study medication.

If **YES**: - Check if they have taken 80% or more of their Polycap study medication since the last visit. If not, please encourage compliance.

- Record the dose of the Polycap study medication he/she has been taking for the last week. If this dose is different from the dose prescribed at the last scheduled study visit, provide the reason for this change using the most appropriate code from the following table:

01	Dizziness	**05**	Cough
02	Low blood pressure/hypotension	**06**	Wheezing
03	Muscle pain	**99**	Other (please specify)
04	Muscle weakness		

- If a new bottle of Polycap study medication was dispensed for this dose change, please complete Unscheduled Study Drug Resupply report and record report number.

If **NO**: - Please indicate if this reason for stop was “reported at a previous visit” **or** “new since last visit”.

- If reason is new since last visit, please complete the Off Study Drug report and record report number
- Encourage the participant to restart study drug whenever possible. Please note that even if the participant has stopped taking any of the study drugs; continue regularly scheduled follow-up visits.

6 Week Clinic Visit (Page 1 of 4)

Trial #168 Follow-Up Visit Pg. 1, CRF # 012 6 Week Visit # 003

Participant ID# Centre # Participant # **Initials** F/M/L

6 Week Visit Date: *(6 weeks ± 7 days from randomization)* year/month/day

1. For this visit, did the participant:

- ☐ *Return to clinic*
- ☐ *Provide information by telephone*
- ☐ *Provide information by other means* → *Specify:*
  - ☐ *Primary healthcare provider*
  - ☐ *Relative or friend*
  - ☐ *Other (specify):* _____
- ☐ *Not return/not provide information* → *Why:*
  - ☐ *Refused:*

	No	Yes
to take any of the study medications?	☐	☐
clinic visits?	☐	☐
telephone or mail contact?	☐	☐
third party follow-up?	☐	☐

  - ☐ *Unable to contact* → Did you:

	N/A	No	Yes	# of attempts
phone the participant at home?		☐	☐ →	
phone the participant at work?	☐	☐	☐ →	
go to the participant's house?		☐	☐ →	
contact the primary contact person?		☐	☐ →	
contact the primary healthcare provider?		☐	☐ →	

- ☐ *Died* → **Complete Death Report**

A. MEDICATION ADHERENCE

1. Adherence to Polycap or placebo

a) Is the participant currently taking Polycap or placebo?

- ☐ **Yes** → Since randomization, has the participant taken 80% or more of the prescribed Polycap or placebo?
  - ☐ *No* → *Please encourage compliance*
  - ☐ *Yes*

→ What dose of Polycap or placebo was the participant taking in the last week?

- ☐ *Full dose Polycap/placebo*
- ☐ *Low Dose Polycap/placebo*
- ☐ *Polycap without ACE-I/placebo*
- ☐ *Other, specify:* _____

→ Is this dose of Polycap or placebo different from the dose prescribed at the randomization visit?

☐ *No* ☐ *Yes* → *Reason:* *If Other (99) please specify:* _____

→ Was a new bottle of Polycap or placebo dispensed for this dose change since the last visit?

☐ *No* ☐ *Yes* → Complete Unscheduled Study Medication Resupply Report #

- ☐ **No** → Is this reason for stopping the Polycap or placebo:
  - ☐ *Reported at a previous visit*
  - ☐ *Not yet reported* → Complete Off Study Drug Report #

Please complete and submit form within 3 working days of visit

A. MEDICATION ADHERENCE (continued)

1. b) Indicate the dosage of Polycap or placebo that the participant was prescribed to take from this visit forward and if a new bottle of Polycap/placebo was dispensed. If YES, please record the study drug kit number allocated by the central resupply system.

2. a) Please ask the participant if they are taking their **aspirin** study medication.

If **YES**: - Check if they have taken 80% or more of their aspirin study medication since the last visit. If not, please encourage compliance.
- Record the dose of the aspirin study medication he/she has been taking for the last week. If this dose is different from the dose prescribed at the last scheduled study visit, provide the reason for this change.

If **NO**: - Complete the Off Study Drug Report to report the reason for this stop and record report number
- Encourage the participant to restart study drug whenever possible. Please note that even if the participant has stopped taking any of the study drugs; continue regularly scheduled follow-up visits.

3. a) Please ask the participant are taking their **vitamin D** study medication

If **YES**: - Please ask the participant if they have taken all of their monthly doses since the last visit. If No, please encourage compliance.

If **NO**: - Complete the Off Study Drug Report to report the reason for this stop and record report number
- Encourage the participant to restart study drug whenever possible. Please note that even if the participant has stopped taking any of the study drugs; continue regularly scheduled follow-up visits.

6 Week Clinic Visit (Page 2 of 4)

Trial #168 Follow-Up Visit Pg. 2, CRF # 013 6 Week Visit # 003

Participant ID# [ ][ ][ ] [ ][ ][ ][ ] **Initials** [ ][ ][ ]
Centre # *Participant #* *F/M/L*

1. Adherence to Polycap or placebo (continued)

b) What dose of Polycap or placebo was the participant prescribed to take from this visit forward?

- ☐ *Full dose Polycap/placebo*
- ☐ *Low Dose Polycap/placebo*
- ☐ *Polycap without ACE-I/placebo*
- ☐ *N/A (Currently stopped)*

→ Was resupply required for this change in dose?

- ☐ *No*
- ☐ *Yes* → Please complete Unplanned Study Medication Resupply Report # [ ][ ][ ][ ]

2. Adherence to aspirin or placebo

a) Is the participant currently taking aspirin or placebo?

☐ **Yes** → Since randomization, has the participant taken 80% or more of the prescribed aspirin or placebo?

- ☐ *No* → *Please encourage compliance*
- ☐ *Yes*

→ What dose of aspirin or placebo is the participant currently taking?

☐ *Standard dose (75 mg)/placebo* ☐ *Other, specify:* _____

→ Is this dose of aspirin or placebo different from the dose prescribed at the randomization visit?

☐ *No* ☐ *Yes* → *Reason:* [ ][ ] *If Other (99) please specify:* _____

☐ **No** → Is this reason for stopping the aspirin or placebo:

- ☐ *Reported at a previous visit*
- ☐ *Not yet reported* → Complete Off Study Drug Report # [ ][ ][ ][ ]

b) What dose of aspirin or placebo was the participant prescribed to take from this visit forward?

- ☐ *Standard dose (75 mg)/placebo*
- ☐ *Other, specify:* _____
- ☐ *N/A (Currently stopped)*

3. Adherence to vitamin D or placebo

a) Is the participant currently taking vitamin D or placebo?

☐ **Yes** → Since the last visit, has the participant taken the following monthly doses of prescribed vitamin D or placebo?

	No	*Yes*	
i) Randomization	☐	☐	→ *If No, please encourage compliance*
ii) 1 Month	☐	☐	

☐ **No** → Is this reason for stopping the aspirin or placebo:

- ☐ *Reported at a previous visit*
- ☐ *Not yet reported* → Complete Off Study Drug Report # [ ][ ][ ][ ]

Please complete and submit form within 3 working days of visit

B. EVENTS SINCE RANDOMIZATION

1. Please refer to event form facing pages for specific event definitions. Please respond YES or NO to all questions. If YES, please record associated report number (if applicable), complete and submit event report.
   f) Revascularization procedure includes PCI or CABG
   n) Suspected unexpected serious adverse reactions (SUSARs) are those that are deemed serious (causing death, life threatening, caused new or prolonged hospitalization, permanently disabling, or medically important); are not predefined study endpoints; are unexpected (in terms of drug labeling and participant's history); and are causally associated with any of the study medications.
   o) If YES to sepsis/infection, please provide the date of sepsis/infection, the principle organ of diagnosis, and indicate YES or NO to antibiotic therapy and hospitalization.
   p) If YES to muscle pain or weakness possibly related to statin therapy, please indicate if CK has been measured and if so, please provide the date of test, value obtained and upper limit of normal for CK.
   q) If YES to deep vein thrombosis, please indicate if participant received blood thinners, date and modality of diagnosis.
   r) If YES to pulmonary embolism, please indicate if the participant received blood thinners, date and modality of diagnosis

6 Week Clinic Visit (Page 3 of 4)

Trial #168 Follow-Up Visit Pg. 3, CRF # 014 6 Week Visit # 003

Participant ID# ☐☐☐ ☐☐☐☐ **Initials** ☐☐☐
Centre # *Participant #* *F/M/L*

B. EVENTS SINCE RANDOMIZATION

1. Have any of the following events occurred since randomization?

	No	Yes		Report #
a) MI	☐	☐	→ Complete MI Report	☐☐☐☐
b) Stroke/TIA	☐	☐	→ Complete Stroke/TIA Report	☐☐☐☐
c) Heart failure	☐	☐	→ Complete Heart Failure Report	☐☐☐☐
d) Surgical procedure	☐	☐	→ Complete Medical Procedure Report	☐☐☐☐
e) Other hospitalization	☐	☐	→ Complete Hospitalization Report	☐☐☐☐
f) Revascularization procedure or amputation	☐	☐	→ Complete Medical Procedure Report	☐☐☐☐
g) Resuscitated cardiac arrest	☐	☐	→ Complete Hospitalization Report	☐☐☐☐
h) Angina	☐	☐	→ Complete Angina Report	☐☐☐☐
i) New diagnosis of diabetes	☐	☐	→ Complete Newly Diagnosed Diabetes Report	
j) New diagnosis/recurrence of cancer	☐	☐	→ Complete Cancer Report	☐☐☐☐
l) Fracture	☐	☐	→ Complete Fracture Report	☐☐☐☐
m) Clinically significant bleeding	☐	☐	→ Complete Bleeding Report	☐☐☐☐
n) Suspected Unexpected Serious Adverse Reaction (SUSAR)	☐	☐	→ Complete SUSAR Report	☐☐☐☐

o) Sepsis/infection ☐ *No* ☐ *Yes* → Date: ☐☐☐☐ ☐☐ ☐☐ → *Complete o) i) to ii) below*
year/month/day

i) Principle organ of diagnosis *(specify)*: _____ ii) Antibiotic therapy ☐ *No* ☐ *Yes*

p) Muscle pain or weakness ☐ *No* ☐ *Yes* → Has CK been measured? ☐ *No* ☐ *Yes* → *Complete p) i) and ii) below*

i) Date of test: ☐☐☐☐ ☐☐ ☐☐ ii) Results: *Value* ☐☐☐☐ *U/L* → *Upper Limit of Normal* ☐☐☐☐ *U/L*
year/month/day

q) Deep vein thrombosis ☐ *No* ☐ *Yes* → Date of diagnosis: ☐☐☐☐ ☐☐ ☐☐ → *Complete q) i) and ii) below*
year/month/day

i) Did the participant receive blood thinners? ☐ *No* ☐ *Yes*

ii) Modality of diagnosis: ☐ leg venography ☐ ultrasonography ☐ autopsy ☐ other, specify: _____

r) Pulmonary embolism ☐ *No* ☐ *Yes* → Date of diagnosis: ☐☐☐☐ ☐☐ ☐☐ → *Complete r) i) and ii) below*
year/month/day

i) Did the participant receive blood thinners? ☐ *No* ☐ *Yes*

ii) Modality of diagnosis: ☐ positive pulmonary angiogram ☐ positive spiral CT scan with a non-filling chest ☐ V/Q lung scan ☐ autopsy ☐ other, specify: _____

Please complete and submit form within 3 working days of visit

C. LOCAL LABORATORY TEST RESULTS

Please ensure the following local safety blood test results are completed at the time of the 6-Week visit:

- serum creatinine
- CK
- ALT or AST
- potassium

Please refer to the protocol and Manual of Operations for instructions on managing elevated values obtained from safety blood tests, if applicable.

D. PHYSICAL MEASUREMENTS

1. Measure blood pressure.

Manual Blood Pressure Monitoring:

- Use a sphygmomanometer
- Ask the participant to remove tight-fitting clothing from his/her arm
- The participant must be sitting for at least 5 minutes prior to first reading
- Put the participant's arm through the cuff loop, making sure the bottom edge of the cuff is approximately one-half inch (1.25 cm) above the elbow crease and the bladder or the cuff is centred over the brachial artery
- The entire cuff should be evenly tight around the participant's arm
- Ask the participant to remain still until the measurement is complete
- Increase the pressure cuff rapidly to 30 mmHg above the level at which the radial pulse is extinguished
- Place the bell (or diaphragm) of the stethoscope over the brachial artery. Open the control value of the sphygmomanometer and deflate the cuff at approximately 2 mmHg per heart beat.
- Read the systolic level (the first appearance of a clear tapping sound - phase I Korotkoff) and the diastolic level (the point at which the sound dissapears - phase V Korotkoff)

Automatic Blood Pressure Monitoring:

- Use the Omron Blood Pressure Monitor.
- Ask the participant to remove tight fitting clothing from his/her arm.
- The participant must be sitting for $\geq$ 5 minutes
- Put the participant's arm through the cuff loop making sure the bottom edge of the cuff is approximately one-half inch (1.25 cm) above the elbow and the arrow on the cuff is above the brachial artery.
- The entire cuff should be evenly tight around the participant's arm. Ask the participant to remain still until the measurement is complete.
- Press the ON/OFF button. After the heart symbol (♥) appears on the digital panel, press the START button. After the measurement is complete, the monitor will display the systolic and diastolic blood pressures and pulse. The cuff will automatically deflate.
- Take 2 readings on the right arm at least 1-minute apart.
- Record all readings on 6W 4

- The participant must be sitting for 3 additional minutes prior to 2nd reading and again, prior to 3rd reading

- Please record the time (24-hour clock) at which each blood pressure reading was taken.

2. Measure heart rate.

E. SCHEDULED FOLLOW-UP

1. The second interim telephone call should be scheduled 3 months ($\pm$ 14 days) from the date of the Randomization visit to reinforce adherence to study medication.
2. The 6-month visit should be scheduled 6 months ($\pm$ 14 days) from the date of the Randomization visit.

PERSON COMPLETING REPORT

Please record the name of the person completing the report and the date completed (YYYY-MM-DD).

6 Week Clinic Visit (Page 4 of 4)

Trial #168 Follow-Up Visit Pg. 4, CRF # 015 6 Week Visit # 003

Participant ID# ☐☐☐ ☐☐☐☐ **Initials** ☐☐☐
Centre # *Participant #* *F/M/L*

B. EVENTS SINCE LAST VISIT (Continued)

1. Have any of the following events occurred since the last visit?

r) Has the participant fallen and landed on the floor or ground, or, fallen and hit an object like a table or chair?

☐ *No* ☐ *Yes* → Complete Fall Report No. ☐☐☐☐

s) Has the participant been involved in a motor vehicle accident as either the driver, passenger or pedestrian?

☐ *No* ☐ *Yes* → Complete Motor Vehicle Accident Report ☐☐☐☐

C. LOCAL LABORATORY TEST RESULTS

1. **Date of collection:** ☐☐☐☐ ☐☐ ☐☐ → **Lab Results Shuttle Form** ☐☐☐☐
year/month/day

	Value		*Upper Limit of Normal*
a) Serum creatinine	☐☐☐.☐☐	☐ *mg/dL* ☐ *µmol/L*	☐☐☐.☐☐
b) CK	☐☐☐☐.☐☐	☐ *U/L* ☐ *µkat/L*	☐☐☐☐.☐☐
c) ☐ ALT or ☐ AST	☐☐☐.☐☐	☐ *U/L* ☐ *µkat/L*	☐☐☐.☐☐
d) Potassium	☐☐.☐	☐ *mEq/L* ☐ *mmol/L*	

D. PHYSICAL MEASUREMENTS

	Right arm blood pressure *Systolic*	*Diastolic*	**Time of Reading** ***(24-hour clock)***	**Heart rate** *beats/minute*
1. Manual reading # 1: Participant seated quietly for 5 minutes	☐☐☐	☐☐☐ *mmHg*	☐☐:☐☐	
2. Automatic (OMRON) reading # 2: Wait for 3 minutes	☐☐☐	☐☐☐ *mmHg*	☐☐:☐☐	☐☐☐
3. Automatic (OMRON) Reading # 3: Wait for 3 minutes	☐☐☐	☐☐☐ *mmHg*	☐☐:☐☐	☐☐☐

E. SCHEDULED FOLLOW-UP

1. Scheduled Date of 2nd Interim Telephone Call: *(3 months ± 14 days after randomization)* ☐☐☐☐ ☐☐ ☐☐
year/month/day

2. Scheduled Date of 6 Month Visit: *(6 months ± 14 days after randomization)* ☐☐☐☐ ☐☐ ☐☐
year/month/day

Name of Person completing report: _____ Date form completed: ☐☐☐☐ ☐☐ ☐☐
year/month/day

Please complete and submit form within 3 working days of visit