

DSCI: Dichotomous Outcomes Form

PLEASE READ BEFORE STARTING:

- *N(included)* refers to either the number of participants included in a group of a controlled-clinical trial (CCT) or the number of participants randomized in a group in a randomized-controlled trial (RCT).

- Please do not indicate any units (including percentage signs) in the table cells. Numbers may be inputted to 2 decimal places, if that is the precision level reported in a study.

RefID: _____

Select the outcome:

Complete a separate form for each relevant outcome reported in the study.

- Abdominal aortic aneurysm
- Activated partial thromboplastin time (aPTT) (above/below threshold). Indicate threshold. _____
- Acute coronary syndrome
- Adherence to prescribed cardiovascular drug regimen
- Adverse Event Other (other than neurologic, allergic, gastrointestinal, bleeding, withdrawal due to adverse event). Please specify. _____
- Alanine transaminase (ALT) (Raised)
- Allergic reactions (All types)
- Amputation
- Anaphylaxis/allergic shock
- Anemia
- Ankle-brachial index (above/below threshold). Indicate threshold. _____
- Arrhythmia (All types)
- Aspartate aminotransferase (AST) (Raised)
- Asthma
- Atrial fibrillation
- Bleeding time (above/below threshold). Indicate threshold. _____
- Blood urea nitrogen (BUN) (Raised)
- Carotid artery disease (not measured by IMT or Doppler). Please specify. _____
- Carotid dilation/stenting
- Carotid intima-media thickness (IMT), as measured by Doppler ultrasound (above/below threshold). Indicate threshold. _____
- Claudication (pain walking)

- Clotting time (above/below threshold). Indicate threshold. _____
- Composite cardiovascular outcome (e.g. MI + Stroke + Vascular Death). Please specify. _____
- Congestive heart/cardiac failure
- Constipation
- Coronary artery bypass graft (CABG)
- Coronary/cerebral arterial calcification score (above/below threshold). Indicate threshold. _____
- C-reactive protein (above/below threshold). Indicate threshold. _____
- Creatinine (Raised)
- Diarrhea
- Ejection fraction (above/below threshold). Indicate threshold. _____
- Electrocardiographic (ECG) measurements or 24 hr ambulatory ECG/Holter monitoring. Please specify outcome. _____
- Fasting blood glucose (above/below threshold). Indicate threshold. _____
- Flatulence
- Gastrointestinal (GI) adverse events (All types)
- Gastrointestinal bleed (All types)
- Gastrointestinal bleed (Lower)
- Gastrointestinal bleed (Upper)
- Glycosylated hemoglobin (above/below threshold). Indicate threshold. _____
- Heart block
- Heartburn
- Hematologic abnormality. Please specify outcome. _____
- Hematuria
- Hemorrhagic stroke
- High-density lipoprotein cholesterol (HDL-C) (above/below threshold). Indicate threshold. _____
- Hospitalization
- Hospitalization (Prolonged)
- Hypertension (HTN), new or worsening (e.g. need for change in therapy)
- Hypotension
- Internal bleed (All types)
- International normalized ratio (INR) (above/below threshold). Indicate threshold.
- Intracerebral bleed
- Intracranial bleed
- Intraventricular bleed
- Leukopenia

- Limb thrombosis/Leg ischemia
- Lipoprotein A (Lp(a)) (above/below threshold). Indicate threshold.

- Liver damage/hepatitis
- Low-density lipoprotein cholesterol (LDL-C) (above/below threshold). Indicate threshold.

- Lymphopenia
- Mesenteric ischemia
- Metabolic syndrome
- Mortality (All-cause)
- Myocardial infarction (All types)
- Myocardial infarction (Fatal)
- Myocardial infarction (Non-fatal)
- Nausea
- Nausea and Vomiting (combined)
- Neurologic adverse events (All types)
- Neuropathy
- Neutropenia
- Non-HDL-C. specify threshold

- Obesity
- Organ toxicity
- Percutaneous transluminal coronary angioplasty (PTCA/PCI/stenting)
- Peripheral revascularization (+/- stent)
- Platelet aggregability (above/below threshold). Indicate outcome and threshold.

- Prolonged QT interval
- Prothrombin time (above/below threshold). Indicate threshold.

- Quality of Life
- Rash
- Ratio of BUN/creatinine (Raised)
- Renal replacement therapy (e.g. dialysis)
- Seizures
- Serious adverse events (composite outcome)
- Stroke (All types)
- Stroke (Fatal)
- Subretinal hemorrhage
- Sudden death
- Syncope

- Thrombocytopenia
- Thrombotic/Ischemic stroke
- Total cholesterol (above/below threshold). Indicate threshold. _____
- Transient ischemic attack (TIA)
- Triglycerides (above/below threshold). Indicate threshold. _____
- Unstable angina
- Valve replacement
- Valvular disease. Please specify outcome. _____
- Vascular death
- Ventricular fibrillation
- Ventricular tachycardia
- Vomiting
- Withdrawal due to adverse events
- Other. Please specify _____

Definition of outcome if reported:

Other description of outcome:

Length of longest randomized followup (from baseline) (days)
 (1 week = 7 days and 1 month = 30 days)

INDIVIDUAL GROUP DATA (Longest randomized post treatment followup)

Group 1 (select one)

- Coenzyme Q10. Other details if needed (e.g. dose). _____
- Echinacea. Other details if needed (e.g. dose). _____
- Fish/marine oils. Other details if needed (e.g. dose). _____
- Garlic. Other details if needed (e.g. dose). _____
- Ginger. Other details if needed (e.g. dose). _____
- Gingko biloba. Other details if needed (e.g. dose). _____
- Ginseng. Other details if needed (e.g. dose). _____
- Hawthorn. Other details if needed (e.g. dose). _____
- Magnesium. Other details if needed (e.g. dose). _____
- Niacin. Other details if needed (e.g. dose). _____
- Omega-3 (EPA, DHA, or both). Other details if needed (e.g. dose). _____
- Red yeast rice. Other details if needed (e.g. dose). _____

- Resveratrol. Other details if needed (e.g. dose). _____
- Vitamin A. Other details if needed (e.g. dose). _____
- Vitamin D. Other details if needed (e.g. dose). _____
- Vitamin D + Calcium. Other details if needed (e.g. dose). _____
- Vitamin E. Other details if needed (e.g. dose). _____
- Vitamin K. Other details if needed (e.g. dose). _____
- Other supplement (intervention group). Please specify. _____
- CONTROL: No treatment (aside from CVD drug) _____
- CONTROL: Placebo _____
- CONTROL: Other dietary supplement. Please specify. _____

N(included) _____

N(analyzed) _____

n1(subjects free of event at baseline) _____

n2(subjects with event) _____

n3(events) _____

n2/N(analyzed) (%) _____

Complete only if reported in the study (do not calculate). Only report the percentage number (without the % sign).

Event Risk (n2/n1)(%) _____

Complete only if reported in the study (do not calculate). Only report the percentage number (without the % sign).

Group 2 (select one)

- Coenzyme Q10. Other details if needed (e.g. dose). _____
- Echinacea. Other details if needed (e.g. dose). _____
- Fish/marine oils. Other details if needed (e.g. dose). _____
- Garlic. Other details if needed (e.g. dose). _____
- Ginger. Other details if needed (e.g. dose). _____
- Ginkgo biloba. Other details if needed (e.g. dose). _____
- Ginseng. Other details if needed (e.g. dose). _____
- Hawthorn. Other details if needed (e.g. dose). _____
- Magnesium. Other details if needed (e.g. dose). _____
- Niacin. Other details if needed (e.g. dose). _____
- Omega-3 (EPA, DHA, or both). Other details if needed (e.g. dose). _____
- Red yeast rice. Other details if needed (e.g. dose). _____
- Resveratrol. Other details if needed (e.g. dose). _____

- Vitamin A. Other details if needed (e.g. dose). _____
- Vitamin D. Other details if needed (e.g. dose). _____
- Vitamin D + Calcium. Other details if needed (e.g. dose). _____
- Vitamin E. Other details if needed (e.g. dose). _____
- Vitamin K. Other details if needed (e.g. dose). _____
- Other supplement (intervention group). Please specify. _____
- CONTROL: No treatment (aside from CVD drug) _____
- CONTROL: Placebo _____
- CONTROL: Other dietary supplement. Please specify. _____

N(included) _____

N(analyzed) _____

n1(subjects free of event at baseline) _____

n2(subjects with event) _____

n3(events) _____

n2/N(analyzed) (%) _____

*Complete only if reported in the study (do not calculate).
Only report the percentage number (without the % sign).*

Event Risk (n2/n1)(%) _____

*Complete only if reported in the study (do not calculate).
Only report the percentage number (without the % sign).*

Group 3 (select one)

- Coenzyme Q10. Other details if needed (e.g. dose). _____
- Echinacea. Other details if needed (e.g. dose). _____
- Fish/marine oils. Other details if needed (e.g. dose). _____
- Garlic. Other details if needed (e.g. dose). _____
- Ginger. Other details if needed (e.g. dose). _____
- Gingko biloba. Other details if needed (e.g. dose). _____
- Ginseng. Other details if needed (e.g. dose). _____
- Hawthorn. Other details if needed (e.g. dose). _____
- Magnesium. Other details if needed (e.g. dose). _____
- Niacin. Other details if needed (e.g. dose). _____
- Omega-3 (EPA, DHA, or both). Other details if needed (e.g. dose). _____
- Red yeast rice. Other details if needed (e.g. dose). _____
- Resveratrol. Other details if needed (e.g. dose). _____
- Vitamin A. Other details if needed (e.g. dose). _____
- Vitamin D. Other details if needed (e.g. dose). _____
- Vitamin D + Calcium. Other details if needed (e.g. dose). _____
- Vitamin E. Other details if needed (e.g. dose). _____
- Vitamin K. Other details if needed (e.g. dose). _____

- Other supplement (intervention group). Please specify. _____
- CONTROL: No treatment (aside from CVD drug) _____
- CONTROL: Placebo _____
- CONTROL: Other dietary supplement. Please specify. _____

N(included) _____

N(analyzed) _____

n1(subjects free of event at baseline) _____

n2(subjects with event) _____

n3(events) _____

n2/N(analyzed) (%) _____

*Complete only if reported in the study (do not calculate).
Only report the percentage number (without the % sign).*

Event Risk (n2/n1)(%) _____

*Complete only if reported in the study (do not calculate).
Only report the percentage number (without the % sign).*

Group 4 (select one)

- Coenzyme Q10. Other details if needed (e.g. dose). _____
- Echinacea. Other details if needed (e.g. dose). _____
- Fish/marine oils. Other details if needed (e.g. dose). _____
- Garlic. Other details if needed (e.g. dose). _____
- Ginger. Other details if needed (e.g. dose). _____
- Gingko biloba. Other details if needed (e.g. dose). _____
- Ginseng. Other details if needed (e.g. dose). _____
- Hawthorn. Other details if needed (e.g. dose). _____
- Magnesium. Other details if needed (e.g. dose). _____
- Niacin. Other details if needed (e.g. dose). _____
- Omega-3 (EPA, DHA, or both). Other details if needed (e.g. dose). _____
- Red yeast rice. Other details if needed (e.g. dose). _____
- Resveratrol. Other details if needed (e.g. dose). _____
- Vitamin A. Other details if needed (e.g. dose). _____
- Vitamin D. Other details if needed (e.g. dose). _____
- Vitamin D + Calcium. Other details if needed (e.g. dose). _____
- Vitamin E. Other details if needed (e.g. dose). _____
- Vitamin K. Other details if needed (e.g. dose). _____
- Other supplement (intervention group). Please specify. _____
- CONTROL: No treatment (aside from CVD drug) _____
- CONTROL: Placebo _____
- CONTROL: Other dietary supplement. Please specify. _____

N(included) _____

N(analyzed) _____

n1(subjects free of event at baseline) _____

n2(subjects with event) _____

n3(events) _____

n2/N(analyzed) (%) _____

*Complete only if reported in the study (do not calculate).
Only report the percentage number (without the % sign).*

Event Risk (n2/n1)(%) _____

*Complete only if reported in the study (do not calculate).
Only report the percentage number (without the % sign).*

ESTIMATES OF GROUP DIFFERENCES

<u>Group 1 (select one)</u>	<u>VS.</u>	<u>Group 2 (select one)</u>	<u>Other details if needed (e.g., dose)</u>
<input type="checkbox"/> Coenzyme Q10		<input type="checkbox"/> Coenzyme Q10	_____
<input type="checkbox"/> Echinacea		<input type="checkbox"/> Echinacea	_____
<input type="checkbox"/> Fish/marine oils		<input type="checkbox"/> Fish/marine oils	_____
<input type="checkbox"/> Garlic		<input type="checkbox"/> Garlic	_____
<input type="checkbox"/> Ginger		<input type="checkbox"/> Ginger	_____
<input type="checkbox"/> Gingko biloba		<input type="checkbox"/> Gingko biloba	_____
<input type="checkbox"/> Ginseng		<input type="checkbox"/> Ginseng	_____
<input type="checkbox"/> Hawthorn		<input type="checkbox"/> Hawthorn	_____
<input type="checkbox"/> Magnesium		<input type="checkbox"/> Magnesium	_____
<input type="checkbox"/> Niacin		<input type="checkbox"/> Niacin	_____
<input type="checkbox"/> Omega-3 (EPA / DHA / both)		<input type="checkbox"/> Omega-3 (EPA / DHA / both)	_____
<input type="checkbox"/> Red yeast rice		<input type="checkbox"/> Red yeast rice	_____
<input type="checkbox"/> Resveratrol		<input type="checkbox"/> Resveratrol	_____
<input type="checkbox"/> Vitamin A		<input type="checkbox"/> Vitamin A	_____
<input type="checkbox"/> Vitamin D		<input type="checkbox"/> Vitamin D	_____
<input type="checkbox"/> Vitamin D + Calcium		<input type="checkbox"/> Vitamin D + Calcium	_____
<input type="checkbox"/> Vitamin E		<input type="checkbox"/> Vitamin E	_____
<input type="checkbox"/> Vitamin K		<input type="checkbox"/> Vitamin K	_____
<input type="checkbox"/> Other supplement (intervention group)		<input type="checkbox"/> Other supplement (intervention group)	_____
<input type="checkbox"/> CONTROL: No treatment (aside from CVD drug)		<input type="checkbox"/> CONTROL: No treatment (aside from CVD drug)	_____

treatment (aside from CVD drug)

CONTROL: Placebo

CONTROL: Other dietary supplement. Please specify.

treatment (aside from CVD drug)

CONTROL: Placebo

CONTROL: Other dietary supplement. Please specify.

Crude Event Risk Ratio

95% CI - lower

95% CI - upper

p-value

Crude Event Odds Ratio

95% CI - lower

95% CI - upper

p-value

Adjusted Event Risk Ratio

95% CI - lower

95% CI - upper

p-value

Adjusted Event Odds Ratio

95% CI - lower

95% CI - upper

p-value

Group 2 (select one) VS.

Group 3 (select one)

Other details if needed (e.g., dose)

Coenzyme Q10

Echinacea

Fish/marine oils

Garlic

Ginger

Gingko biloba

Ginseng

Hawthorn

Magnesium

Niacin

Omega-3 (EPA / DHA / both)

Red yeast rice

Resveratrol

Vitamin A

Vitamin D

Vitamin D + Calcium

Vitamin E

Vitamin K

Other supplement

Coenzyme Q10

Echinacea

Fish/marine oils

Garlic

Ginger

Gingko biloba

Ginseng

Hawthorn

Magnesium

Niacin

Omega-3 (EPA / DHA / both)

Red yeast rice

Resveratrol

Vitamin A

Vitamin D

Vitamin D + Calcium

Vitamin E

Vitamin K

Other supplement

(intervention group)

CONTROL: No treatment (aside from CVD drug)

CONTROL: Placebo

CONTROL: Other dietary supplement. Please specify.

(intervention group)

CONTROL: No treatment (aside from CVD drug)

CONTROL: Placebo

CONTROL: Other dietary supplement. Please specify.

Crude Event Risk Ratio

95% CI - lower

95% CI - upper

p-value

Crude Event Odds Ratio

95% CI - lower

95% CI - upper

p-value

Adjusted Event Risk Ratio

95% CI - lower

95% CI - upper

p-value

Adjusted Event Odds Ratio

95% CI - lower

95% CI - upper

p-value

COMMENTS