

DSCI: Continuous 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.

Select the outcome:

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

- Activated partial thromboplastin time (aPTT)
- Aggregation time
- Alanine transaminase (ALT)
- Anemia: Other parameter (e.g. ferritin, MCV, MCH). Specify outcome.
- Anemia: Serum iron level
- Ankle-brachial index
- Area under the concentration curve (AUC)
- Arterial blood pressure
- Aspartate aminotransferase (AST)
- Bioavailability (F)
- Bleeding time
- Blood urea nitrogen (BUN)
- Body mass index (BMI)
- Carotid intima-media thickness (IMT), as measured by Doppler ultrasound
- Change in 10-year Framingham risk profile
- Clearance (Cl: volume of blood cleared of drug per unit time)
- Clotting time
- Concentration of drug transport proteins
- Coronary/cerebral arterial calcification score
- C-reactive protein (CRP)
- Creatinine
- Diastolic blood pressure (DBP)
- Ejection fraction
- Elimination rate constant (Kel) or Fraction of drug eliminated per unit time

- Fasting blood glucose
 - Glomerular filtration rate (GFR)
 - Glycosylated hemoglobin (HbA1c)
 - Half-life (T1/2)
 - High-density lipoprotein cholesterol (HDL-C)
 - International normalized ratio (INR)
 - Leukpenia: WBC count
 - Lipoprotein A (Lp(a))
 - Low-density lipoprotein cholesterol (LDL-C)
 - Lymphopenia: Lymphocyte level
 - Maximum concentration (Cmax)
 - Neutropenia: Neutrophilic granulocyte count (ANC)
 - Non-HDL-C
 - Platelet aggregability. Specify outcome.
 - Platelet count
 - Prothrombin time (PT)
 - Quality of Life
 - Ratio of BUN/creatinine
 - Systolic blood pressure (SBP)
 - Time to reach maximum concentration (Tmax)
 - Total cholesterol
 - Triglycerides
 - Volume of distribution (Vd)
 - Other. Please specify.
-

Definition of outcome if reported:

Other description of outcome:

Units _____

Length of longest randomized followup (from baseline)
(days-- each week = 7 days; each 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)	_____	Mean	_____	Median	_____
N(analyzed)	_____	SD	_____	IQR – low	_____
		SE	_____	IQR – high	_____

Mean Change from baseline	_____	% change in mean	_____	Difference in median OR	_____
SD	_____	SD	_____	Difference in median %	_____
SE	_____	SE	_____	IQR – lower	_____
95% CI – lower	_____	95% CI – lower	_____	IQR - upper	_____
95% CI – upper	_____	95% CI – upper	_____	95% CI – lower	_____
p-value	_____	p-value	_____	95% CI – upper	_____
				p-value	_____

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). _____
- 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)	_____	Mean	_____	Median	_____
N(analyzed)	_____	SD	_____	IQR – low	_____
		SE	_____	IQR – high	_____
Mean Change from baseline	_____	% change in mean	_____	Difference in median OR	_____
				Difference in median %	_____
SD	_____	SD	_____	IQR – lower	_____
SE	_____	SE	_____	IQR - upper	_____
95% CI – lower	_____	95% CI – lower	_____	95% CI – lower	_____
95% CI – upper	_____	95% CI – upper	_____	95% CI – upper	_____
p-value	_____	p-value	_____	p-value	_____

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)	_____	Mean	_____	Median	_____
N(analyzed)	_____	SD	_____	IQR – low	_____
		SE	_____	IQR – high	_____
Mean Change from baseline	_____	% change in mean	_____	Difference in median OR	_____
				Difference in median %	_____
SD	_____	SD	_____	IQR – lower	_____
SE	_____	SE	_____	IQR - upper	_____
95% CI – lower	_____	95% CI – lower	_____	95% CI – lower	_____
95% CI – upper	_____	95% CI – upper	_____	95% CI – upper	_____
p-value	_____	p-value	_____	p-value	_____

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). _____
- 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)	_____	Mean	_____	Median	_____
N(analyzed)	_____	SD	_____	IQR – low	_____
		SE	_____	IQR – high	_____

Mean Change from baseline	_____	% change in mean	_____	Difference in median OR Difference in median %	_____
SD	_____	SD	_____	IQR – lower	_____
SE	_____	SE	_____	IQR - upper	_____
95% CI – lower	_____	95% CI – lower	_____	95% CI – lower	_____
95% CI – upper	_____	95% CI – upper	_____	95% CI – upper	_____
p-value	_____	p-value	_____	p-value	_____

ESTIMATES OF GROUP DIFFERENCES

Has an adjusted analysis been presented for this outcome?

- Yes. If yes, list the variables that were adjusted for. _____
- No

Crude Estimates

<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)	_____
<input type="checkbox"/> CONTROL: Placebo	<input type="checkbox"/> CONTROL: Placebo	_____
<input type="checkbox"/> CONTROL: Other dietary supplement. Please specify.	<input type="checkbox"/> CONTROL: Other dietary supplement. Please specify.	_____

Crude Difference in Means	_____	Crude Difference in % mean change	_____	Crude difference in medians OR crude difference in median %	_____
SD	_____	SD	_____	IQR – low	_____
SE	_____	SE	_____	IQR – high	_____
95% CI - lower	_____	95% CI – lower	_____	95% CI – lower	_____
95% CI - upper	_____	95% CI – upper	_____	95% CI – upper	_____
p-value	_____	p-value	_____	p-value	_____

Adjusted Estimates

<u>Group 1 (select one)</u>	VS.	<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) | _____ |
| <input type="checkbox"/> CONTROL: Placebo | <input type="checkbox"/> CONTROL: Placebo | _____ |
| <input type="checkbox"/> CONTROL: Other dietary supplement. Please specify. | <input type="checkbox"/> CONTROL: Other dietary supplement. Please specify. | _____ |

Adjusted Difference in Means _____

SD _____

SE _____

95% CI - lower _____

95% CI - upper _____

p-value _____

Adjusted Difference in % mean change _____

SD _____

SE _____

95% CI - lower _____

95% CI - upper _____

p-value _____

Adjusted difference in medians OR adjusted difference in median % _____

IQR - low _____

IQR - high _____

95% CI - lower _____

95% CI - upper _____

p-value _____

Group 1 (select one) VS.

- Coenzyme Q10
- Echinacea
- Fish/marine oils
- Garlic
- Ginger
- Gingko biloba
- Ginseng
- Hawthorn

Group 3 (select one)

- Coenzyme Q10
- Echinacea
- Fish/marine oils
- Garlic
- Ginger
- Gingko biloba
- Ginseng
- Hawthorn

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

- | | | |
|---|---|-------|
| <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) | _____ |
| <input type="checkbox"/> CONTROL: Placebo | <input type="checkbox"/> CONTROL: Placebo | _____ |
| <input type="checkbox"/> CONTROL: Other dietary supplement. Please specify. | <input type="checkbox"/> CONTROL: Other dietary supplement. Please specify. | _____ |

Adjusted Difference in Means _____

SD _____

SE _____

95% CI - lower _____

95% CI - upper _____

p-value _____

Adjusted Difference in % mean change _____

SD _____

SE _____

95% CI - lower _____

95% CI - upper _____

p-value _____

Adjusted difference in medians OR adjusted difference in median % _____

IQR - low _____

IQR - high _____

95% CI - lower _____

95% CI - upper _____

p-value _____

Group 2 (select one) VS.

Group 3 (select one)

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

- | | | |
|---|---|-------|
| <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)	_____
<input type="checkbox"/>	CONTROL: Placebo	<input type="checkbox"/>	CONTROL: Placebo	_____
<input type="checkbox"/>	CONTROL: Other dietary supplement. Please specify.	<input type="checkbox"/>	CONTROL: Other dietary supplement. Please specify.	_____

Adjusted Difference in Means _____

SD _____

SE _____

95% CI - lower _____

95% CI - upper _____

p-value _____

Adjusted Difference in % mean change _____

SD _____

SE _____

95% CI – lower _____

95% CI – upper _____

p-value _____

Adjusted difference in medians OR adjusted difference in median % _____

IQR – low _____

IQR – high _____

95% CI – lower _____

95% CI – upper _____

p-value _____

Comments