# DSCI: General Characteristics Form for Experimental Studies

Indicate NR if not reported and NA if not applicable. For percentages, just indicate the number without the percentage sign.

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1. RefID: _____

2. Is subgroup data available?

*Please see supplemental guidance for data extraction.*
***If the answer is yes, please also fill out a separate form for each subgroup for which data have been presented.***

- ❑ Yes

  3. If yes, **ONLY ANSWER IF THIS IS A <u>SUBGROUP FORM</u>:** Check the subgroup to which this form applies.

  - ❑ Age >= 65
  - ❑ Age >= 80
  - ❑ Ethnicity
  - ❑ Gender
  - ❑ Healthy Adults
  - ❑ Participants with disorders of the liver (e.g., hepatitis, cirrhosis)
  - ❑ Diabetes
  - ❑ Participants with disorders of the kidney (e.g., reduced GFR, end stage renal disease)
  - ❑ CVD drug for non-CVD indication
  - ❑ Genetic polymorphisms

  4. If yes, **ONLY ANSWER IF THIS IS A <u>SUBGROUP FORM</u>:** Indicate the CHD risk level of the subgroup.

  *Please refer to supplemental guidance for data extraction.*

  - ❑ At low risk for CHD (0-1 risk factor)
  - ❑ At moderate/moderately high risk for CHD (2+ risk factors)
  - ❑ At high risk for CHD
  - ❑ Mixed (please specify)
  - ❑ Unclear

- ❑ No

5. Does the study contain subgroups of subjects with either low, moderate, or high CHD risk?

*Please see supplemental guidance for data extraction.*
***If the answer is yes, please also fill out a separate form for each CHD risk level subgroup presented.***

- ❑ Yes

  6. If yes, **ONLY ANSWER IF THIS IS A <u>CHD RISK LEVEL SUBGROUP FORM</u>: Check the CHD risk subgroup to which this form applies.**

  - ❑ At low risk for CHD (0-1 risk factor)
  - ❑ At moderate/moderately high risk for CHD (2+ risk factors)
  - ❑ At high risk for CHD

- ❑ No

7. Are any of the following presented as study-level covariates? (DO NOT ANSWER IF THIS IS A SUBGROUP FORM)

*Please see supplemental guidance for data extraction.*

- ❑ Age >= 65 years
- ❑ Age >=80 years
- ❑ Ethnicity
- ❑ Gender
- ❑ Healthy adults
- ❑ Participants with disorders of the liver (e.g. hepatitis, cirrhosis)
- ❑ Diabetes
- ❑ Participants with disorders of the kidney (e.g. reduced GFR, end stage renal disease)
- ❑ CVD drug for non-CVD indication
- ❑ Genetic polymorphisms
- ❑ None

8. Indicate the CHD risk level of the entire study population: (DO NOT ANSWER IF THIS IS A SUBGROUP FORM)

*Please see supplemental guidance for data extraction.*

- ❑ At low risk for CHD (0-1 risk factors)
- ❑ At moderate/moderately high risk for CHD (2+ risk factors)
- ❑ At high risk for CHD
- ❑ Mixed (please specify)
- ❑ Unclear

9. Author (Smith, JA): _____

10. Year of Publication _____

11. Ref IDs of Companions _____

12. Source of Funding (was the study supported by industry?)

*Please see supplemental guidance for data extraction.*

- ❑ Yes
- ❑ No
- ❑ Unclear

13. Region

- ❑ North America
- ❑ Central & South America
- ❑ Europe
- ❑ East Asia
- ❑ Rest of Asia
- ❑ Africa
- ❑ Australia/New Zealand
- ❑ Middle East
- ❑ Multiple regions (please describe)

  _____

- ❑ Other (please describe)

  _____

- ❑ Not reported

14. Setting

- ❑ General community
- ❑ Primary care
- ❑ Speciality clinic
- ❑ Mixed or other (please describe)

  _____

- ❑ Not reported

15. List of inclusion criteria

_____

16. List of Exclusion Criteria

_____

17. Brief Summary of Population (include important risk factors): E.g. Elderly diabetic subjects with angina.

_____

18. Study Design

- ❑ Parallel randomized-controlled trial (RCT)

- ❑ Crossover RCT
- ❑ Pre-crossover RCT
- ❑ Controlled clinical trial (CCT)

19. Run-in Period (days): _____

20. Duration of Treatment (days) _____

21. Duration of Treatment in Period 2 (days) *FOR CROSSOVER TRIALS ONLY* _____

22. Wash-Out Period (days) *FOR CROSSOVER TRIALS ONLY* _____

23. Duration of Followup - measured from end of intervention (days) _____

24. Duration of Longest Followup (days) (i.e., the last followup point, which may include a long-term followup in the same study or a secondary publication) *Please refer to supplemental guidelines for data extraction* _____

25. With respect to intention-to-treat, select the statement that best describes the method used in the study.

- ❑ Intention-to-treat analysis (all randomized or initially enrolled)
- ❑ Only subjects who received treatment at start of the study
- ❑ Only subjects with followup data (who completed the study)
- ❑ Other (please describe)

_____

- ❑ Unclear

❑ Not reported

26. Number screened (number of subjects screened initially using eligibility criteria)- NR if no data: _____

27. Number included (CCTs) or randomized _____

28. Number analyzed (number of subjects included in the analysis of results) _____

29. Was the number of dropouts or withdrawals reported?

- ❑ Yes (If yes, answer the next two questions below)

30. If yes, total number of dropouts or withdrawals:

Intervention Group 1 _____

Intervention Group 2 _____

Control Group _____

All Groups Combined _____

31. If yes, dropouts or withdrawals due to adverse events:

Intervention Group 1 _____

Intervention Group 2 _____

Control Group _____

All Groups Combined _____

- ❑ No

# DETAILED POPULATION CHARACTERISTICS

**AGE**

*Please see supplemental guidelines for data extraction and refer to formulas for calculating pooled means and SDs.*

32. Pooled mean age (years) _____
33. Pooled age SD (years) _____
34. Pooled age SE (years) _____
35. Median age (years) _____
36. Age: IQR-low (years) _____
37. Age: IQR-high (years) _____
38. Age: lower 95% CI (years) _____
39. Age: upper 95% CI (years) _____
40. Age range (min-max) (years) _____

**GENDER**

41. Percentage of female subjects _____

**ETHNICITY**

42. Select the ethnicities that were included in the study, and provide percentages.
    - ❑ Caucasian _____
    - ❑ African-American _____
    - ❑ Hispanic _____
    - ❑ Asian _____
    - ❑ Native American _____
    - ❑ African _____
    - ❑ Other (please describe and provide percentage) _____
    - ❑ Not reported _____

**MORBIDITIES**

43. Indicate why subjects were taking CVD drug(s)
    - ❑ Cardiovascular indication
    - ❑ Non-cardiovascular indication(s) (please specify)
    - ❑ Both (please describe)

      _____

    - ❑ Other (please describe)

      _____

44. Did subjects have other comorbidities?
    - ❑ Yes (please list)

❑ No

❑ Not reported

**OTHER CO-INTERVENTIONS**

45. List of concomitant non-CVD medications taken by participants.

46. Was a dietary modification intervention administered?

❑ Yes (please describe)

❑ No

❑ Not reported

47. Was an exercise intervention administered?

❑ Yes (please describe)

❑ No

❑ Not reported

48. Was any other type of lifestyle intervention administered?

❑ Yes (please describe)

❑ No

❑ Not reported

**DESCRIPTION OF CONTROL GROUP**

49. What did the control group receive?

❑ Placebo. If the study provides further description of the placebo, please describe.

❑ No treatment

❑ Another type of dietary supplement (please specify)

**DESCRIPTION OF INTERVENTION GROUP: DIETARY SUPPLEMENT(S)**

50. Supplement (select one)

❑ Omega -3 (EPA, DHA or both)

❑ Fish oils/marine oils

❑ Magnesium

❑ Garlic

❑ Ginko biloba

❑ Ginseng

- ❑ Vitamin E
- ❑ Vitamin K
- ❑ Vitamin A
- ❑ Vitamin D
- ❑ Vitamin D + Calcium
- ❑ Hawthorn
- ❑ Echinacea
- ❑ Coenzyme Q10
- ❑ Red yeast rice
- ❑ Niacin
- ❑ Resveratrol

51. Latin or other names used in this study for the supplement (e.g., Crataegus oxyacantha for Hawthorn)

_____

52. Supplement Composition (e.g., % DHA + %EPA)

_____

53. Is purity of the supplement reported?

- ❑ Yes (please describe - Please see supplemental guidance)

_____

- ❑ No

54. Is the supplement licensed in the region used?

- ❑ Yes
- ❑ No
- ❑ Not reported

55. Does the paper report where the supplement was manufactured?

- ❑ Yes (please describe)

_____

- ❑ No

56. Have storage conditions (e.g., temperature) for the supplement been reported?

- ❑ Yes (please describe - Please see supplemental guidance)

_____

- ❑ No

56. Is the origin of the supplement reported (e.g. plant leaves)?

- ❑ Yes (please describe)

_____

- ❑ No

58. Administered dosage of the supplement (indicate units, e.g. IU/day or mg/day)

_____

59. What form was the supplement administered in?

- ❑ Capsule/Tablet
- ❑ Liquid
- ❑ Topical
- ❑ Mixed (please describe)

_____

- ❑ Other (please describe)
- ❑ _____
- ❑ Not reported

60. What subtype of the supplement was administered? (e.g., carotenoid for Vitamin A; salt-form such as citrate for magnesium)

_____

61. Are nutrient levels or biomarkers of the supplement reported (e.g., in blood or urine)?
*Please see supplemental guidance*

- ❑ Yes (please describe)

_____

- ❑ No

62. Is there a second intervention group?

- ❑ Yes (If yes, provide details of this supplement by answering the questions below.)

63. Supplement 2 (select one)

- ❑ Omega-3 (EPA, DHA or both)
- ❑ Fish oils/marine oils
- ❑ Magnesium
- ❑ Garlic
- ❑ Ginko biloba
- ❑ Ginseng
- ❑ Ginger
- ❑ Vitamin E
- ❑ Vitamin K
- ❑ Vitamin A
- ❑ Vitamin D
- ❑ Vitamin D + Calcium
- ❑ Hawthorn
- ❑ Echinacea
- ❑ Coenzyme Q10
- ❑ Red yeast rice
- ❑ Niacin

❑ Resveratrol

64. Latin or other names used in this study for supplement 2 (e.g., Crataegus oxyacantha for Hawthorn)

_____

65. Supplement 2 Composition (e.g., % DHA + %EPA)

_____

66. Is purity of supplement 2 reported?

❑ Yes (please describe - Please see supplemental guidance)

_____

❑ No

67. Is supplement 2 licensed in the region used?

❑ Yes

❑ No

❑ Not reported

68. Does the paper report where supplement 2 was manufactured?

❑ Yes (please describe)

_____

❑ No

69. Have storage conditions (e.g., temperature) for supplement 2 been reported?

❑ Yes (please describe - Please see supplemental guidance)

_____

❑ No

70. Is the origin of supplement 2 reported (e.g. plant leaves)?

❑ Yes (please describe)

_____

❑ No

71. Administered dosage of supplement 2 (indicate units, e.g. IU/day or mg/day)

_____

72. What form was supplement 2 administered in?

- ❑ Capsule/Tablet
- ❑ Liquid
- ❑ Topical
- ❑ Mixed (please describe)

_____

- ❑ Other (please describe)
- ❑ _____
- ❑ Not reported

73. What subtype of supplement 2 was administered? (e.g., carotenoid for Vitamin A; salt-form such as citrate for magnesium)

_____

74. Are nutrient levels or biomarkers of supplement 2 reported (e.g., in blood or urine)?
*Please see supplemental guidance*

- ❑ Yes (please describe)

_____

- ❑ No

❑ No

**CVD DRUG(S) (Control and Intervention Groups)**

75. Brand name of CVD drug (used by >80% of study sample)

_____

76. Chemical name of CVD drug (used by >80% of study sample):

_____

77. Drug Category/Class:

- ❑ b-blockers
- ❑ Calcium channel blockers
- ❑ Alpha-blockers
- ❑ Antiarrhythmics
- ❑ Inotropics
- ❑ Anticoagulants
- ❑ Antiplatelets
- ❑ RAAS Antagonist: ACEI

- ❑ RAAS Antagonist: ARB
- ❑ RAAS Antagonist: Renin Inhibitor
- ❑ RAAS Antagonist: Aldosterone-Receptor Antagonist
- ❑ Antilipidemic: HMG Co-A Reductase Inhibitor
- ❑ Antilipidemic: Fibrate
- ❑ Antilipidemic: Bile acid sequestrant
- ❑ Antilipidemic: Other
- ❑ Diuretic: Thiazide/Thiazide-like
- ❑ Diuretic: Loop
- ❑ Diuretic: Other
- ❑ Vasodilator: Central/Direct
- ❑ Vasodilator: Nitrates/PDE-5 Inhibitors
- ❑ Vasodilator: Other

78. Mode of administration of CVD drug:

- ❑ Oral
- ❑ Parenteral
- ❑ Patch
- ❑ Other (please indicate)

_____

79. Starting administered dosage of CVD drug (mg/day): _____

80. Final administered dosage of CVD drug (mg/day): _____

81. Mean administered dosage of CVD drug (mg/day): _____

82. Is the duration of treatment with this CVD drug the same as the supplement?

- ❑ Yes
- ❑ No
- ❑ Unclear

83. Was a second CVD drug administered to > 80% of the study sample?

- ❑ Yes (If yes, provide details of this drug by answering the questions below)

84. Brand name of CVD drug 2 (used by >80% of study sample)

_____

85. Chemical name of CVD drug 2 (used by >80% of study sample):

_____

86. Drug Category/Class (for CVD drug 2):

- ❑ b-blockers
- ❑ Calcium channel blockers
- ❑ Alpha-blockers
- ❑ Antiarrhythmics
- ❑ Inotropics
- ❑ Anticoagulants
- ❑ Antiplatelets
- ❑ RAAS Antagonist: ACEI
- ❑ RAAS Antagonist: ARB
- ❑ RAAS Antagonist: Renin Inhibitor
- ❑ RAAS Antagonist: Aldosterone-Receptor Antagonist
- ❑ Antilipidemic: HMG Co-A Reductase Inhibitor
- ❑ Antilipidemic: Fibrate
- ❑ Antilipidemic: Bile acid sequestrant
- ❑ Antilipidemic: Other
- ❑ Diuretic: Thiazide/Thiazide-like
- ❑ Diuretic: Loop
- ❑ Diuretic: Other
- ❑ Vasodilator: Central/Direct
- ❑ Vasodilator: Nitrates/PDE-5 Inhibitors
- ❑ Vasodilator: Other

87. Mode of administration of CVD drug 2:

- ❑ Oral
- ❑ Parenteral
- ❑ Patch
- ❑ Other (please indicate)

_____

88. Starting administered dosage of CVD drug 2 (mg/day): _____

89. Final administered dosage of CVD drug 2 (mg/day): _____

90. Mean administered dosage of CVD drug 2 (mg/day): _____

91. Is the duration of treatment with this CVD drug 2 the same as the supplement?

- ❑ Yes
- ❑ No
- ❑ Unclear

❑ No

92. Was a third CVD drug administered to > 80% of the study sample?

❑ Yes (If yes, provide details of this drug by answering the questions below)

93. Brand name of CVD drug 3 (used by >80% of study sample)

_____

94. Chemical name of CVD drug 3 (used by >80% of study sample):

_____

95. Drug Category/Class (for CVD drug 3):

- ❑ b-blockers
- ❑ Calcium channel blockers
- ❑ Alpha-blockers
- ❑ Antiarrhythmics
- ❑ Inotropics
- ❑ Anticoagulants
- ❑ Antiplatelets
- ❑ RAAS Antagonist: ACEI
- ❑ RAAS Antagonist: ARB
- ❑ RAAS Antagonist: Renin Inhibitor
- ❑ RAAS Antagonist: Aldosterone-Receptor Antagonist
- ❑ Antilipidemic: HMG Co-A Reductase Inhibitor
- ❑ Antilipidemic: Fibrate
- ❑ Antilipidemic: Bile acid sequestrant
- ❑ Antilipidemic: Other
- ❑ Diuretic: Thiazide/Thiazide-like
- ❑ Diuretic: Loop
- ❑ Diuretic: Other
- ❑ Vasodilator: Central/Direct
- ❑ Vasodilator: Nitrates/PDE-5 Inhibitors
- ❑ Vasodilator: Other

96. Mode of administration of CVD drug 3:

- ❑ Oral
- ❑ Parenteral
- ❑ Patch
- ❑ Other (please indicate)

_____

97. Starting administered dosage of CVD drug 3 (mg/day): _____

98. Final administered dosage of CVD drug 3 (mg/day): _____

99. Mean administered dosage of CVD drug 3 (mg/day): _____

100. Is the duration of treatment with this CVD drug 3 the same as the supplement?

- ❑ Yes
- ❑ No
- ❑ Unclear

❑ No

101. **OTHER COMMENTS**