

SOLVD

ELIGIBILITY VISIT FORM

VERSION B / 9-1-1986

TEMP ID:

FORM: S E F VERSION: B VISIT: 1

INSTRUCTIONS:

This form is to be used only at Visit 1, the SOLVD Eligibility Visit. Print clearly when entering a response in the appropriate boxes. For multiple choice questions, circle the one appropriate letter corresponding to the response chosen. Specific instructions for various questions are enclosed in boxes directly below the question. See the SOLVD General Instructions for Completing Forms for details.

SOLVD ELIGIBILITY VISIT FORM (screen 1 of 12) (SEF page 1 of 8)

A. IDENTIFYING INFORMATION

1. Today's Date: / /

Month Day Year

2.1. Last Name:

2.2. First Name:

2.3. Middle Name:

2.4. Third Name:

(maiden, initial, etc.)

3.1. Street Address:

3.2. City:

3.3. State/Province.....

3.4. Country:

3.5. Zip Code/Canadian or European Postal Code:

4. Telephone Number (Home):

- -

Hospital Information

5.1. Hospital Name:

8.3. Employer's Street Address:

| | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
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8.4. City:

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8.5. State/Province.....

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8.6. Country:

| | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
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8.7. Zip Code/Canadian or European Postal Code:

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|--|--|--|--|--|--|--|--|--|--|
| | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|

8.8. Employer's Telephone Number:

| | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
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|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

Participant Information

9. Sex.....Male M
Female F

10. Ethnic Identity.....American Indian 1
Asian 2
Black 3
Caucasian 4
Hispanic 5
Other 6

11. Date of Birth:

| | | | | | | | |
|-------|--|---|-----|--|---|------|--|
| | | / | | | / | | |
| Month | | | Day | | | Year | |

12. Social Security Number:

| | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| | | | | - | | | | | | | | | | | | | | | |
|--|--|--|--|---|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|

13.4. Is the qualifying Ejection Fraction the most recent?.....Yes Y
No N

If Yes, go to Question 15.1. on page 5.

B. ENTRY CRITERION

13.1. Qualifying Ejection Fraction (EF) Percentage.....

| | |
|--|--|
| | |
|--|--|

14.1. Most recent Ejection Fraction Percentage.....

| | |
|--|--|
| | |
|--|--|

13.2. Date of Ejection Fraction Measurement:

| | | | | | | | |
|-------|--|---|-----|--|---|------|--|
| | | / | | | / | | |
| Month | | | Day | | | Year | |

14.2. Date of most recent Ejection Fraction measurement:

| | | | | | | | |
|-------|--|---|-----|--|---|------|--|
| | | / | | | / | | |
| Month | | | Day | | | Year | |

13.3. Method Utilized.....

Radionuclide R
Contrast Angiography A
2-D Echo E

14.3. Method utilized for the most recent Ejection Fraction measurement....

Radionuclide R
Contrast Angiography A
2-D Echo E

C. EXCLUSION CRITERIA (Circle the appropriate response for each item. All items must be indicated.)

| | Yes | No | | Yes | No |
|---|-----|----|---|-----|----|
| 15.1. History of intolerance to enalapril..... | Y | N | 15.6. Complex congenital heart disease..... | Y | N |
| 15.2. Currently taking ACE inhibitor and unable to discontinue..... | Y | N | 15.7. Syncopal episodes presumed to be due to life threatening arrhythmias..... | Y | N |
| 15.3. Myocardial Infarction within 30 days of expected date of randomization..... | Y | N | 15.8. Any major cardiac surgery likely. | Y | N |
| 15.4. Hemodynamically significant valvular or outflow tract obstruction..... | Y | N | 15.9. Unstable angina pectoris..... | Y | N |
| 15.5. Constrictive Pericarditis..... | Y | N | 15.10. Uncontrolled hypertension..... | Y | N |
| | | | 15.11. Cor Pulmonale..... | Y | N |
| | | | 15.12. Advanced pulmonary disease..... | Y | N |

C. EXCLUSION CRITERIA (Circle the appropriate response for each item. All items must be indicated.)

| | Yes | No | | Yes | No |
|---|-----|----|---|-----|----|
| 15.13. Major neurological disease..... | Y | N | 15.21. Significant primary liver disease..... | Y | N |
| 15.14. Cerebrovascular disease..... | Y | N | 15.22. Likely to be nonadherent (alcoholism, drug addiction, lack of a fixed address, etc.).. | Y | N |
| 15.15. Collagen vascular disease..... | Y | N | 15.23. Other life-threatening disease or not realistically expected to be discharged alive. | Y | N |
| 15.16. Suspected significant renal artery stenosis..... | Y | N | 15.24. Woman likely to bear children... | Y | N |
| 15.17. Renal failure..... | Y | N | 15.25. Other investigational drug protocols..... (except compassionate use) | Y | N |
| 15.18. Cancer..... | Y | N | 15.26. Failure to give consent..... | Y | N |
| 15.19. Immunosuppressive therapy..... | Y | N | | | |
| 15.20. Active myocarditis..... | Y | N | | | |

D. INITIALS OF PERSON COMPLETING THIS FORM

16. Initials.....

If Yes (the participant is suitable for SOLVD), continue with F. PHYSICAL EXAMINATION, Question 18.1.

If No, EXIT THE FORM

E. STUDY SUITABILITY

17. Is the participant suitable for participation in SOLVD?.....Yes Y
 No N

NOTE: The participant is suitable for SOLVD only if all of the responses to questions 15.1. thru 15.26. (C. EXCLUSION CRITERION) are N (No).

F. PHYSICAL EXAMINATION

Blood Pressure (supine)

18.1. Systolic..... mm Hg

18.2. Diastolic..... mm Hg

Blood Pressure (sitting)

19.1. Systolic..... mm Hg

19.2. Diastolic..... mm Hg

Heart rate (beats per minute)

20.1. Supine.....

20.1. Sitting.....

23. Sodium (Na)..... meq/l

24. Potassium (K)..... meq/l

G. LABORATORY DATA

21. Hematocrit (HCT)..... %

25. Blood Urea Nitrogen (BUN).. mg/dl

26. Creatinine..... mg/dl

22.1. Total White Blood Count (WBC x1000).....

27a. Proteinuria.....negative 0
 trace or + 1
 ++ 2
 +++ 3
 ++++ 4

22.2. Percent Neutrophils.....

22.3. Percent Lymphocytes.....

31. New York Heart Association
 CHF Classification..... 1
 2
 3
 4

NOTE: If the participant is taking a vasodilator for heart failure (other than oral nitrate) or is NYHA Class 4 or has known Sodium (Na) less than 130 meq/l, then the participant is to be hospitalized for 24 hrs. for blood pressure monitoring. Complete the SOLVD Medication Monitoring Form.

32. Is the participant's
 known Sodium (Na) level
 less than 130 meq/l?.....Yes Y
 No N

33.1a. Is the participant presently
 taking hydralazine or
 isosorbide medication?.....Yes Y
 No N

If Yes, go to OPTIONAL DATA FOR
 LOCAL CLINIC USE ONLY below.

33.2a. If No (not taking hydralazine
 or isosorbide), what is the
 likelihood that these drugs
 would be used if the
 participant's condition worsens?...

Likely A
 Unlikely B

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

a) Number of pills dispensed
at this visit.....

1st attempt

2nd attempt

b) Scheduled date of Visit 2:

Month

Day

Year