

SOLVD ELIGIBILITY VISIT FORM

VERSION A / 5-22-86

TEMP ID:

FORM: S E F

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 11) (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:

2.2. 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:

8.4. City:

8.5. State/Province.....

8.6. Country:

8.7. Zip Code/Canadian or European Postal Code:

8.8. Employer's Telephone Number:

- -

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.....

20.2. 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).....

27. Proteinuria..... negative 0
 + 1
 ++ 2
 +++ 3
 ++++ 4

22.2. Percent Neutrophils.....

22.3. Percent Lymphocytes.....

H. MEDICATION TOLERANCE MONITORING

28.1. Is the participant taking isosorbide medication?.....Yes Y
 No N

If No, go to Question 29.1.

28.2. If Yes, enter the daily dose (milligrams) of medication.....

29.1. Is the participant taking any vasodilator medication other than isosorbide?.....Yes Y
 No N

If No, go to Question 31.

If Yes, indicate below:

Circle: Y (Yes) or N (No) for each medication. If Yes, enter the total daily dose (milligrams) for that medication.

Medication	Yes/No	Total Daily Dose (mg)
29.2. Prazosin	a) Y N	b) <input type="text"/> <input type="text"/>
29.3. Hydralazine	a) Y N	b) <input type="text"/> <input type="text"/> <input type="text"/>
29.4. Nifedipine	a) Y N	b) <input type="text"/> <input type="text"/> <input type="text"/>
29.5. Other	a) Y N	

NOTE: If the participant is continuing the use of a non-ACE vasodilator, please consider discontinuing the use unless the indication is clear.

30.1. Is the participant discontinuing the use of all non-ACE vasodilators?.....Yes Y
 No N

If Yes, go to Question 31.

30.2. If No (continuing), specify the indication:

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

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

NOTE: If the participant is taking a vasodilator (other than isosorbide) 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 medication monitoring. Complete the SOLVD Medication Monitoring Form.

33.1. Is the participant not taking hydralazine or isosorbide medication?.....Yes Y
 No N

If No, go to page 8.

33.2. If Yes (not taking hydralazine or isosorbide), what is the likelihood that these drugs would be used if the participant's condition worsens?....
 Highly likely A
 Moderately likely B
 Unlikely C

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