

SOLVD

BASELINE VISIT FORM

VERSION C / 12-28-1987

TEMP ID:

FORM: S B F VERSION: C VISIT: 3

INSTRUCTIONS:

This form is to be used only at Visit 3, the SOLVD Baseline Visit (Randomization). 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 BASELINE VISIT FORM (screen 1 of 12) (SBF page 1 of 7)

A. IDENTIFYING INFORMATION

1. Today's Date: // //
Month Day Year

2.1. Last Name:

2.2. First Name:

2.3. Middle Name:

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

a) Date of Visit 2: // //
Month Day Year

b) Number of days since Visit 2.....

c) Number of pills dispensed at Visit 2..

d) Number of pills returned today.....

e) Adherence.....

B. EVALUATION OF ELIGIBILITY

3.1. Did the participant take 80% or more tablets in the run-in period?.....Yes Y
No N

$$\text{Adherence} = \frac{(c) - (d)}{2 \times (b)} \times 100$$

3.2. Is the participant's condition stable?.....Yes Y
 No N

3.3. Does this participant still meet the inclusion criteria?.....Yes Y
 No N

If Yes, go to Question 4.

3.3a. If No, enter the number of the most important exclusion criterion not met.....

NOTE: Enter the number (01-26) of the exclusion criterion from the SOLVD Eligibility Visit Form. These are listed on the right.

C. INITIALS OF PERSON COMPLETING THIS FORM

4. Initials.....

EXCLUSION CRITERIA:

- 1 = History of intolerance to enalapril
- 2 = Currently taking ACE inhibitor and unable to stop
- 3 = MI within 30 days of expected randomization
- 4 = Hemodynamically significant valvular or outflow tract obstruction
- 5 = Constrictive pericarditis
- 6 = Complex congenital heart disease
- 7 = Syncopal episodes due to life-threatening arrhythmias
- 8 = Any major cardiac surgery likely
- 9 = Unstable angina pectoris
- 10 = Uncontrolled hypertension
- 11 = Cor pulmonale
- 12 = Advanced pulmonary disease
- 13 = Major neurological disease
- 14 = Cerebrovascular disease
- 15 = Collagen vascular disease
- 16 = Suspected significant renal artery stenosis
- 17 = Renal failure
- 18 = Cancer
- 19 = Immunosuppressive therapy
- 20 = Active myocarditis
- 21 = Significant primary liver disease
- 22 = Likely to be nonadherent (alcoholism, drug addiction, lack of a fixed address, etc.)
- 23 = Other life-threatening disease or not expected to be discharged alive
- 24 = Woman likely to bear children
- 25 = Other investigational drug protocols (except compassionate use)
- 26 = Failure to give consent

D. TRIAL SUITABILITY

4a. Was the participant given a second chance for the adherence to placebo?.....Yes Y
 No N

NOTE: In order for the participant to be eligible for SOLVD, Questions 3.1., 3.2. and 3.3. must be Yes (Y).

5. Is the participant still suitable for randomization?.....Yes Y
 No N

If Yes (the participant is still suitable for randomization), continue with section E. CLINICAL HISTORY, Question 6.

If No, EXIT THE FORM.

E. CLINICAL HISTORY

6. Does the participant have angina?.....Yes Y
 No N

7. Has the participant had dizzy spells?.....Yes Y
 No N

8. Has the participant fainted (syncope)?.....Yes Y
 No N

9.1. Has the participant ever smoked cigarettes?.....Yes Y
 No N

If No, go to Question 10.

9.2. Does the participant currently smoke?.....Yes Y
 No N

If Yes, go to Question 10.

9.3. If No (stopped smoking), how many months ago did you stop smoking?.....

10. Average number of alcoholic drinks consumed per week in the past two years....

11.1. Previous myocardial infarction?.....Yes Y
 No N

If No go to Question 12.

11.2. If Yes, enter date of most recent myocardial infarction:
 // //
 Month Day Year

12. Permanent pacemaker?.....Yes Y
 No N

13a. Previous cardiac surgery or percutaneous transluminal coronary angioplasty (PCTA) ?.....Yes Y
 No N

If No, go to Question 14.1.

13b. If Yes, date of most recent cardiac surgery or PCTA:
 // //
 Month Day Year

13c. If Yes, type of procedure:
 coronary artery bypass graft C
 valve replacement V
 PCTA A
 Other O

Past History of the following?

	Yes	No
14.1. Hypertension.....	Y	N
14.2. Diabetes mellitus.....	Y	N
14.3. Chronic obstructive pulmonary disease.....	Y	N
14.4. Cerebrovascular accident.....	Y	N
14.5. Angina pectoris.....	Y	N
14.6. Orthopnea.....	Y	N
14.7. Edema.....	Y	N
14.8. Breathlessness on exertion....	Y	N
14.9. Atrial fibrillation, supraventricular tachyarrhythmia, or atrial flutter?	Y	N

F. NON-STUDY MEDICATIONS CURRENTLY USED

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

	Yes	No
15. Digitalis.....	Y	N
16. Other inotropic agent.....	Y	N
17.1. Diuretic.....	Y	N
<div style="border: 1px solid black; padding: 2px; display: inline-block;"> If No (diuretics), go to Question 18. </div>		
17.2. Thiazide.....	Y	N
17.3. Loop.....	Y	N
17.4. Metolazone.....	Y	N
17.5. Potassium sparing.....	Y	N

Name/Dosage/Frequency

NON-STUDY MEDICATIONS CURRENTLY USED

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

	Yes	No
18. Antiarrhythmic.....	Y	N
19. Regular use of antiplatelet..	Y	N
20. Beta Blocker.....	Y	N
21.1. Vasodilator / ACE-inhibitor..	Y	N
<div style="border: 1px solid black; padding: 2px; display: inline-block;"> If No (vasodilators), go to Question 23. </div>		
21.2. Long acting nitrate.....	Y	N
21.3. Captopril	Y	N
[IF YES, EXIT FORM]		
21.4. Enalapril.....	Y	N

Name/Dosage/Frequency

NON-STUDY MEDICATIONS CURRENTLY USED

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

	Yes	No
21.5. Other ACE inhibitor.....	Y	N
[IF YES, EXIT FORM]		
22. Calcium channel blocker.....	Y	N
22.1. Other vasodilator.....	Y	N
23. Anti-hypertensive (other than above).....	Y	N
24. Anticoagulant.....	Y	N
25. Potassium supplementation....	Y	N

Name/Dosage/Frequency

26. Is the participant using non-ACE vasodilators?.....	Yes	Y
If No, go to Question 27.1	No	N

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

26.1. Is the participant discontinuing the use of all non-ACE vasodilators?....	Yes	Y
If Yes, go to Question 27.1.	No	N

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

G. QUALIFYING EJECTION FRACTION

27.1. EF Percentage.....

27.2. Date Obtained:

		/			/		
Month			Day			Year	

The following drugs are classified as other ANTIHYPERTENSIVES: Beta Blockers, Guanabenz Acetate, Rescinnamine, Guanethidine, Reserpine, Alpha Methyl Dopa

The following drugs are classified as VASODILATORS: Nitrates, Calcium Channel Blockers, Prazosin, Minoxidil, Clonidine, Hydralazine

L. NEW YORK HEART ASSOCIATION CHF CLASSIFICATION

38. NYHA class..... 1
 2
 3
 4

39. For which Trial is this participant being considered?....

Prevention P

Treatment T

NOTE: At this point the participant is ready to be randomized. Complete the SOLVD Randomization Form and attempt to randomize the participant. Continue with this form if the randomization was successful or unsuccessful.

M. RANDOMIZATION INFORMATION

38a. Is the participant still eligible for randomization?.....Yes Y
 No N

If Yes, go to Question 39.

40. Was the participant eligible for randomization?....

Yes Y

No N

If No, EXIT THE FORM and review the SOLVD Randomization Procedures.

38b. If No, specify:

EXIT THE FORM.

41. RANDOMIZATION ID:

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N. MEDICATION DISPENSING / VISIT SCHEDULING

42. Pills dispensed:

Pill type	# Pills dispensed at this visit	Dose (Circle: Q=QD or B=BID)						
2.5 mg	a) <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td></tr></table>					b) <table border="0" style="display: inline-block; vertical-align: middle;"><tr><td>Q</td></tr><tr><td>B</td></tr></table>	Q	B
Q								
B								
5.0 mg	c) <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td></tr></table>					d) <table border="0" style="display: inline-block; vertical-align: middle;"><tr><td>Q</td></tr><tr><td>B</td></tr></table>	Q	B
Q								
B								
10.0 mg	e) <table border="1" style="display: inline-table; width: 60px; height: 20px;"><tr><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td><td style="width: 15px;"></td></tr></table>					f) <table border="0" style="display: inline-block; vertical-align: middle;"><tr><td>Q</td></tr><tr><td>B</td></tr></table>	Q	B
Q								
B								

43. Date of next scheduled visit:

		//			//		
Month	Day		Year				