

SOLVD BASELINE VISIT FORM

VERSION A : 5-23-86

TEMP ID:

FORM: S B F

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 11) (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

1. Did the participant take 80X 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

C. INITIALS OF PERSON COMPLETING THIS FORM

4. Initials.....

D. TRIAL SUITABILITY

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

13.1. Previous cardiac surgery?.....Yes Y
 No N

If No, go to Question 14.1.

13.2. If Yes, date of most recent cardiac surgery:
 / /
 Month Day Year

13.3. If Yes, type of cardiac surgery:
 coronary artery bypass graft C
 valve replacement V
 percutaneous transluminal coronary angioplasty A
 Other O

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

F. NON-STUDY MEDICATIONS CURRENTLY USED			<u>OPTIONAL DATA FOR LOCAL CLINIC USE ONLY</u>	
	Yes	No	Name/Dosage/Frequency	
15. Digoxin.....	Y	N	-----	
16. Other inotropic agent.....	Y	N	-----	
17.1. Diuretic.....	Y	N	-----	
If No (diuretics), go to Question 18.				
17.2. Thiazide.....	Y	N	-----	
17.3. Loop.....	Y	N	-----	
17.4. Metolazone.....	Y	N	-----	
17.5. Potassium sparing.....	Y	N	-----	

NON-STUDY MEDICATIONS CURRENTLY USED			<u>OPTIONAL DATA FOR LOCAL CLINIC USE ONLY</u>	
	Yes	No	Name/Dosage/Frequency	
18. Antiarrhythmic.....	Y	N	-----	
19. Regular use of antiplatelet..	Y	N	-----	
20. Beta Blocker.....	Y	N	-----	
21.1. Vasodilator.....	Y	N	-----	
If No (vasodilators), go to Question 22.				
21.2. Long-acting nitrate.....	Y	N	-----	
21.3. Other vasodilator.....	Y	N	-----	
22. Calcium channel blocker.....	Y	N	-----	

NON-STUDY MEDICATIONS CURRENTLY USED

- | | Yes | No |
|--|-----|----|
| 23. Anti-hypertensive
(other than above)..... | Y | N |
| 24. Anticoagulant..... | Y | N |
| 25. Potassium supplementation.... | Y | 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?.... Y N

If Yes, go to Question 27.1.

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

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

Name/Dosage/Frequency

6. QUALIFYING EJECTION FRACTION RECORDED AT ELIGIBILITY VISIT 1 (SEF FORM)

- 27.1. EF Percentage.....

- 27.2. Date Obtained:

		/			/		
Month			Day			Year	

4. ELECTROCARDIOGRAM

	Yes	No
29. Normal.....	Y	N
29. Atrial fibrillation or atrial flutter.....	Y	N
30. QRS delay \geq 120 ms.....	Y	N
31.1. Left Ventricular Hypertrophy.	Y	N
If No, go to Question 32.1.		
31.2. P wave.....	Y	N
31.3. Amplitude V3 in S & R wave...	Y	N
31.4. ST segment.....	Y	N

I. CHEST X-RAY

32.1. Cardiac-thoracic ratio.....

32.2. Are there any signs of pulmonary venous hypertension?.....

Yes	Y
No	N

J. PHYSICAL EXAMINATION

Weight (without shoes or outdoor garments)

Enter one weight - lbs or kgs

33.1. Weight (to nearest lb.).....

33.2. Weight (to nearest kg.).....

34. Heart rate (sitting).....

Blood Pressure (sitting)

35.1. Systolic..... mm Hg

35.2. Diastolic..... mm Hg

Any of the following present?

	Yes	No
36.1. Rales.....	Y	N
36.2. Edema.....	Y	N
36.3. Elevated jugular venous pressure.....	Y	N
36.4. S3 gallop.....	Y	N

K. PHYSICIAN'S JUDGMENT OF PRIMARY CAUSE OF CONGESTIVE HEART FAILURE

37.1. Primary cause of CHF.....

Ischemic	I
Unknown	U
Other	O

If Ischemic (I) or Unknown (U) go to Question 37.

37.2. If Other, specify:

L. NEW YORK HEART ASSOCIATION CHF CLASSIFICATION

38. NYHA class.....

1	1
2	2
3	3
4	4

M. RANDOMIZATION INFORMATION

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.

40. Was the participant eligible for randomization?.....Yes Y
 No N

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

41. RANDOMIZATION NUMBER:

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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) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	b) <input type="radio"/> Q <input type="radio"/> B
5.0 mg	c) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	d) <input type="radio"/> Q <input type="radio"/> B
10.0 mg	e) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	f) <input type="radio"/> Q <input type="radio"/> B

43. Date of next scheduled visit:

<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>	/	<input type="text"/> <input type="text"/>
Month		Day		Year