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SOLVD

BASELINE VISIT FORM

VERSION B / 9-1-1986

TEMP ID: | | | | | | | | | |

FORM: S B F

VERSION: B

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.

A. IDENTIFYING INFORMATION

1. Today's Date: | | / | | / | | (Month / Day / Year)

2.1. Last Name: | | | | | | | | | | | | | | | | |

2.2. First Name: | | | | | | | | | | | | | | | | |

2.3. Middle Name: | | | | | | | | | | | | | | | | |

B. EVALUATION OF ELIGIBILITY

3.1. Did the participant take 80% or more tablets in the run-in period?.....Yes Y

No N

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..... | | | | %

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

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 inclusion criteriion not met..... ☐☐

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

C. INITIALS OF PERSON COMPLETING THIS FORM

4. Initials..... ☐☐

INCLUSION 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 pericariditis
7 = Syncopal episodes due to life-threatening arrythmias
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

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

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

	Yes	No	Name/Dosage/Frequency
15. Digitalis.....	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

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

	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.			
21.2a. Oral 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

H. ELECTROCARDIOGRAM

28a. Atrial fibrillation.....Yes Y

No N

If Yes, go to Question 28c.

28b. If No, P wave terminal force in V1..... . mv.

28c. QRS delay ≤ 120 ms.....Yes Y

No N

If No, go to section I. CHEST X-RAY, Question 32.1.

28d. Amplitude of R wave in V5 or V6 (whichever is larger).... . mv.

28e. Amplitude of R wave in AVL.. . mv.

28f. Amplitude of R wave in II, III or AVF..... (whichever is largest) . mv.

28g. Amplitude of S wave in V1.... . mv.

28h. Amplitude of S wave in V3.... . mv.

28i. ST segment depression in inferior leads of V5 and V6.. . mv.

I. CHEST X-RAY

32.1. Cardiac-thoracic ratio..... .

32.2. Are there any signs of pulmonary venous congestion on X-ray?.....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)..... (beats per minute)

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

Other O

Unknown U

If Ischemic (I) or Unknown (U) go to Question 38.

37.2. If Other, specify:

L. NEW YORK HEART ASSOCIATION CHF CLASSIFICATION

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

M. RANDOMIZATION INFORMATION

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

If Yes, go to Question 39.

38b. If No, specify:

EXIT THE FORM.

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 ID:

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)	b) Q B
5.0 mg	c)	d) Q B
10.0 mg	e)	f) Q B

43. Date of next scheduled visit:

Month / Day / Year