SOLVD

FOLLOW-UP INTERVIEW / EXAM FORM

VERSION B / 9-1-1986

RAND ID: | | | | | | | | | |

FORM: S F E VERSION: B VISIT: | |

INSTRUCTIONS: This form is to be used at all visits after Visit 3 (Follow-Up visits). 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 FOLLOW-UP INTERVIEW/EXAM FORM (screen 1 of 15) (SFE page 1 of 12)

A. IDENTIFYING INFORMATION

1. Date of this interview/exam: | | / | | / | |
Month Day Year

2. Date of last SOLVD interview/exam: | | / | | / | |
Month Day Year

3.1. Last Name:

3.2. First Name:

3.3. Middle Name:

4.1. Is the participant's address and/or telephone number the same as before?.....
Yes Y
No N

If Yes (the same as before), go to Question 5.1. on page 2.

4.2. Street Address:

4.3. City:

4.4. State/Province..... | |

4.5. Country:

4.6. Zip Code/Canadian or European Postal Code:

4.7. Telephone Number (Home): | | | - | | | | - | | | |

5.1. Is the participant's private physician (name, address and telephone number) the same as before?.....Yes Y

No N

If Yes (the same as before), go to Question 6.1.

5.2. Last Name:

5.3. First Name:

5.4. Street Address:

5.5. City:

5.6. State/Province.....

5.7. Country:

5.8. Zip Code/Canadian or European Postal Code:

5.9. Private physician's telephone number: - -

6.1. Is the participant's employment (name, title, address and telephone number) the same as before?.....Yes Y

No N

If Yes (the same as before), go to Question 7.1. on page 3.

6.2. Name or Status: (company, self-employed, disabled, retired, etc.)

Employment Information

6.3. Participant's Job title:

6.4. Street Address:

6.5. City:

6.6. State/Province.....

6.7. Country:

6.8. Zip Code/Canadian or European Postal code:

6.9. Employer's Telephone Number: - -

B. INTERIM SYMPTOMS AND SIDE EFFECTS

7.1. Since the last SOLVD visit, has the participant had angina?.....Yes Y

No N

If No, go to Question 8.1.

7.2. If Yes, enter the average number of attacks per week..... [ ][ ][ ]

8.1. Has the participant Had dizzy spells?.....Yes Y

No N

8.2. Has the participant fainted (syncope)?.....Yes Y

No N

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

Since your most recent SOLVD interview have you had:

a) Dyspnea on exertion (define in lay terms).....Yes Y

No N

If Yes, rate severity on a scale of 1-4..... [ ]
(4 = most severe)

	Yes	No
b) Orthopnea.....	Y	N
c) PND.....	Y	N
d) Extreme, inappropriate fatigue.	Y	N
e) Edema.....	Y	N

9. Since the last SOLVD visit, was the participant hospitalized?.....Yes Y

No N

If Yes, complete the SOLVD HOSPITALIZATION FORM.

10. Since the last SOLVD visit, has the participant been ill requiring a visit to the physician but not hospitalization?.....Yes Y

No N

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

If Yes to Question 9, diagnosis:

C. NON-STUDY MEDICATIONS CURRENTLY USED

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

	Yes	No	Name/Dosage/Frequency
11. Digitalis.....	Y	N	
12. Other inotropic agent.....	Y	N	
13.1. Diuretic.....	Y	N	
If No (diuretics), go to Question 14.			
13.2. Thiazide.....	Y	N	
13.3. Loop.....	Y	N	
13.4. Metolazone.....	Y	N	
13.5. Potassium sparing.....	Y	N	

NON-STUDY MEDICATIONS CURRENTLY USED

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

	Yes	No	Name/Dosage/Frequency
14. Antiarrhythmic.....	Y	N	
15. Regular use of antiplatelet.....	Y	N	
16. Beta blocker.....	Y	N	
17.1. Vasodilator/ACE-inhibitor.....	Y	N	
If No (vasodilator/ACE), go to Question 18. on page 5.			
17.2a. Oral nitrate.....	Y	N	
17.3. Other vasodilator.....	Y	N	
17.4. Captopril.....	Y	N	

NON-STUDY MEDICATIONS CURRENTLY USED

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

	Yes	No	Name/Dosage/Frequency
17.5. Enalapril.....	Y	N	
17.6. Other ACE-inhibitor.....	Y	N	
18. Calcium channel blocker.....	Y	N	
19. Anti-hypertensive (other than above).....	Y	N	
20. Anticoagulant.....	Y	N	
21. Potassium supplementation.....	Y	N	

D. STUDY MEDICATION

OPTIONAL DATA FOR LOCAL CLINIC USE

22. Pills dispensed/returned:

Instructions: Enter the following information for each pill type dispensed either at the last SOLVD visit or last use of this form: # pills dispensed, dose (Q=QD=once daily, B=BID=twice daily), # pills returned and # days since the last visit

Pill type	# Pills previously dispensed	Dose (Circle: Q=QD or B=BID)	# Pills returned today	# days since last visit
2.5 mg	a)	b) Q B	c)	d)
5.0 mg	e)	f) Q B	g)	h)
10.0 mg	i)	j) Q B	k)	l)

Have the following symptoms been present since the last visit?.....

	Yes	No
23.1. Skin rash.....	Y	N

	Yes	No
23.2. Dizziness/fainting.....	Y	N
23.3. Taste disturbance.....	Y	N
23.4. Blurred Vision.....	Y	N
23.5. Fatigue.....	Y	N
23.6. Nausea.....	Y	N
23.7. Forgetfulness.....	Y	N
23.8. Other.....	Y	N

If No (Other), go to section E. PHYSICAL EXAMINATION, Question 24.1.

If Yes (Other), specify:

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

a) JVP (cm above angle of Louis at 30 degrees):_____

b) Rales.....Yes Y
No N

If Yes, are rales:

i) Unilateral.....Yes Y
No N

ii) Bilateral.....Yes Y
No N

Extent of lung fields (bases(s) only):

≤ 1/2 lung field L
> 1/2 lung field G

c) S3 gallop.....Yes Y
No N

d) Liver span (cm):_____

e) Edema.....Yes Y
No N

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E. PHYSICAL EXAMINATION

Weight (without shoes or outdoor garments)

Enter one weight - lbs or kgs

24.1. Weight in lbs..... . lbs

24.2. Weight in kgs..... . kgs

25. Heart rate (sitting)..... (beats per minute)

Blood Pressure (sitting)

26.1. Systolic..... mm Hg

26.2. Diastolic..... mm Hg

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

F. PHYSICIAN'S ASSESSMENT

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

27. New York Heart Association CHF classification..... 1
2
3
4

28. Which of the following best describes the participant?.....

Circle one number.

A previously asymptomatic participant (Prevention Trial participant who had never previously developed symptoms)..... 1

A previously symptomatic participant (Treatment Trial or Prevention Trial participant who was found to be symptomatic at a previous visit)..... 2

If previously symptomatic (2), go to Question 31. on page 8.

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

29.1. Is there evidence that CHF has developed since the previous visit?.....Yes Y

No N

If No (CHF has not developed), go to section 6. LABORATORY DATA, Question 32. on page 8.

If Yes (CHF has developed), indicate the symptoms of CHF:

	Yes	No
29.2. Shortness of breath at rest/minimal exertion...	Y	N
29.3. Orthopnea/Paroxysmal Nocturnal Dyspnea...	Y	N
29.4. Acute pulmonary edema.....	Y	N
29.5. Fatigue at rest or with minimal exertion....	Y	N

If Yes (CHF has developed), indicate the signs of CHF:

	Yes	No
30.1. Rales.....	Y	N
30.2. Edema.....	Y	N
30.3. Elevated jugular venous pressure.....	Y	N
30.4. S3 gallop.....	Y	N
30.5. Radiologic evidence of pulmonary venous congestion or pulmonary edema or pleural effusions.....	Y	N

Go to section 6. LABORATORY DATA, Question 32.

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

31. If previously symptomatic, the participant's CHF severity since last visit is.....

Improved	I
Unchanged	U
Worsened	W

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

6. LABORATORY DATA

32. Hematocrit (HCT)..... ☐☐ %

33.1. Total White Blood Count (WBC x1000)..... ☐☐

33.2. Percent Neutrophils..... ☐☐

33.3. Percent Lymphocytes..... ☐☐

Serum digoxin level:_____

34. Sodium (Na)..... ☐☐☐ meq/l

35. Potassium (K)..... ☐.☐ meq/l

36. Blood Urea Nitrogen (BUN).. ☐☐ mg/dl

37. Creatinine..... ☐.☐ mg/dl

38a. Proteinuria.....negative 0
trace or + 1
++ 2
+++ 3
++++ 4

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

H. STUDY MEDICATION DISPENSING INFORMATION

39. Pills dispensed:

Pill type		# Pills dispensed at this visit		Dose (Circle one: Q=QD=once daily or B=BID=twice daily)	
2.5 mg	a)	☐☐☐☐	b)	Q / B	
5.0 mg	c)	☐☐☐☐	d)	Q / B	
10.0 mg	e)	☐☐☐☐	f)	Q / B	

40. Has the dosage of study drug been changed since:
1) the last SOLVD visit or
2) use of a SOLVD Alteration in Study Drug Dosage Form?.....

Yes Y
No N

If No (no change), go to section L. SCHEDULING INFORMATION, Question 52. on page 12.

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

I. STUDY DRUG DOSAGE CHANGE

41. Type of change in dosage.....Increase I

Decrease D

If a Decrease (D), go to section K. REASON FOR DECREASING DOSAGE, Question 43.1.

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

J. REASON FOR INCREASING DOSE

42.1. Increase toward prescribed maintenance dose following dose reduction.....Yes Y

No N

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

42.2. Increase toward prescribed maintenance dose by protocol.....Yes Y

No N

42.3. Other.....Yes Y

No N

If No, go to section L. SCHEDULING INFORMATION, Question 52. on page 12.

If Yes (Other), specify:

Go to section L. SCHEDULING INFORMATION, Question 52. on page 12.

K. REASON FOR DECREASING DOSE

43.1. Side effects.....Yes Y

No N

If No (side effects), go to Question 44. on page 11.

If Yes (side effects), indicate the following side effects:

	Yes	No
43.2. Symptomatic hypotension.....	Y	N
43.3. Taste abnormalities.....	Y	N
43.4. Skin rash.....	Y	N
43.5. Azotemia.....	Y	N
43.6. Other.....	Y	N

If No (Other), go to Question 44.

If Yes (Other), specify:

	Yes	No
44. Myocardial Infarction.....	Y	N

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

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	Yes	No
45.1. Cardiac surgery other than transplant....	Y	N

If No, go to Question 46.

45.2. If Yes (cardiac surgery), specify:

	Yes	No
46. Cardiac transplant.....	Y	N
47. Noncardiac surgery.....	Y	N
48. Worsening CHF with need for treatment with "open label" medication identical or similar to the study drug.....	Y	N

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

	Yes	No
49. Requested by the referring physician.....	Y	N
50. Requested by the participant....	Y	N
51. Other.....	Y	N

If No (Other), go to Question 52.

If Yes (Other), specify:

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

L. SCHEDULING INFORMATION

52. Date of next visit:

		/			/

Month Day Year

SOLVD FOLLOW-UP INTERVIEW/EXAM FORM (screen 15 of 15) (SFE page 12 of 12)

M. ORIGIN OF FORM

53. This form was completed.....

At the clinic C

By telephone T

N. INITIALS OF PERSON COMPLETING THIS FORM

54. Initials.....
