

# 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: [Grid]

5.3. First Name: [Grid]

5.4. Street Address: [Grid]

5.5. City: [Grid]

5.6. State/Province..... [Grid]

5.7. Country: [Grid]

5.8. Zip Code/Canadian or European Postal Code: [Grid]

5.9. Private physician's telephone number: [Grid]

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.) [Grid]

Employment Information

6.3. Participant's Job title: [Grid]

6.4. Street Address: [Grid]

6.5. City: [Grid]

6.6. State/Province..... [Grid]

6.7. Country: [Grid]

6.8. Zip Code/Canadian or European Postal code: [Grid]

6.9. Employer's Telephone Number: [Grid]

**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 B.1.

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

B.1. Has the participant  
Had dizzy spells?.....Yes Y

No N

B.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.....

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) <input type="text"/>	b) <input type="text"/> Q <input type="text"/> B	c) <input type="text"/>	d) <input type="text"/>
5.0 mg	e) <input type="text"/>	f) <input type="text"/> Q <input type="text"/> B	g) <input type="text"/>	h) <input type="text"/>
10.0 mg	i) <input type="text"/>	j) <input type="text"/> Q <input type="text"/> B	k) <input type="text"/>	l) <input type="text"/>
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      B

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

d) Liver span (cm): \_\_\_\_\_

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

**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.**

29.1. Is there evidence that  
CHF has developed  
since the previous visit?.....Yes Y  
No N

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

**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:

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) <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

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

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.

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

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

	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

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:


L. SCHEDULING INFORMATION

52. Date of next visit:

<table border="1" style="display: inline-table; width: 30px; height: 20px;"> <tr><td style="width: 15px;"></td><td style="width: 15px;"></td></tr> </table>			/	<table border="1" style="display: inline-table; width: 30px; height: 20px;"> <tr><td style="width: 15px;"></td><td style="width: 15px;"></td></tr> </table>			/	<table border="1" style="display: inline-table; width: 30px; height: 20px;"> <tr><td style="width: 15px;"></td><td style="width: 15px;"></td></tr> </table>		
Month		Day		Year						

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.....

--	--