

# 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.

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 inclusion criterion 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 pericarditis
  - 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

|  |  |
|--|--|
| <p>9.1. Has the participant ever smoked cigarettes?.....Yes Y<br/>No N</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 10px auto;">If No, go to Question 10.</div> <p>9.2. Does the participant currently smoke?.....Yes Y<br/>No N</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 10px auto;">If Yes, go to Question 10.</div> <p>9.3. If No (stopped smoking), how many months ago did you stop smoking?..... <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/></p> <p>10. Average number of alcoholic drinks consumed per week in the past two years.... <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/> <input style="width: 30px;" type="text"/></p> | <p>11.1. Previous myocardial infarction?.....Yes Y<br/>No N</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 10px auto;">If No, go to Question 12.</div> <p>11.2. If Yes, enter date of most recent myocardial infarction:</p> <div style="display: flex; justify-content: center; align-items: center; gap: 20px;"> <div style="text-align: center;"><input style="width: 30px; height: 20px;" type="text"/><br/>Month</div> <div style="text-align: center;">//</div> <div style="text-align: center;"><input style="width: 30px; height: 20px;" type="text"/><br/>Day</div> <div style="text-align: center;">//</div> <div style="text-align: center;"><input style="width: 30px; height: 20px;" type="text"/><br/>Year</div> </div> <p>12. Permanent pacemaker?.....Yes Y<br/>No N</p> |
|--|--|

| <p>13a. Previous cardiac surgery or percutaneous transluminal coronary angioplasty (PCTA) ?.....Yes Y<br/>No N</p> <div style="border: 1px solid black; padding: 2px; width: fit-content; margin: 10px auto;">If No, go to Question 14.1.</div> <p>13b. If Yes, date of most recent cardiac surgery or PCTA:</p> <div style="display: flex; justify-content: center; align-items: center; gap: 20px;"> <div style="text-align: center;"><input style="width: 30px; height: 20px;" type="text"/><br/>Month</div> <div style="text-align: center;">//</div> <div style="text-align: center;"><input style="width: 30px; height: 20px;" type="text"/><br/>Day</div> <div style="text-align: center;">//</div> <div style="text-align: center;"><input style="width: 30px; height: 20px;" type="text"/><br/>Year</div> </div> <p>13c. If Yes, type of procedure:</p> <table style="width: 100%; border: none;"> <tr><td>coronary artery bypass graft</td><td style="text-align: right;">C</td></tr> <tr><td>valve replacement</td><td style="text-align: right;">V</td></tr> <tr><td>PCTA</td><td style="text-align: right;">A</td></tr> <tr><td>Other</td><td style="text-align: right;">O</td></tr> </table> | coronary artery bypass graft | C  | valve replacement | V | PCTA | A | Other | O | <p style="text-align: center;">History of the following?</p> <table style="width: 100%; border: none;"> <thead> <tr> <th></th> <th style="text-align: center;">Yes</th> <th style="text-align: center;">No</th> </tr> </thead> <tbody> <tr><td>14.1. Hypertension.....</td><td style="text-align: center;">Y</td><td style="text-align: center;">N</td></tr> <tr><td>14.2. Diabetes mellitus.....</td><td style="text-align: center;">Y</td><td style="text-align: center;">N</td></tr> <tr><td>14.3. Chronic obstructive pulmonary disease.....</td><td style="text-align: center;">Y</td><td style="text-align: center;">N</td></tr> <tr><td>14.4. Cerebrovascular accident.....</td><td style="text-align: center;">Y</td><td style="text-align: center;">N</td></tr> <tr><td>14.5. Angina pectoris.....</td><td style="text-align: center;">Y</td><td style="text-align: center;">N</td></tr> <tr><td>14.6. Orthopnea.....</td><td style="text-align: center;">Y</td><td style="text-align: center;">R</td></tr> <tr><td>14.7. Edema.....</td><td style="text-align: center;">Y</td><td style="text-align: center;">N</td></tr> <tr><td>14.8. Breathlessness on exertion....</td><td style="text-align: center;">Y</td><td style="text-align: center;">N</td></tr> </tbody> </table> |  | 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 | R | 14.7. Edema..... | Y | N | 14.8. Breathlessness on exertion.... | Y | N |
|--|------------------------------|----|-------------------|---|------|---|-------|---|--|--|-----|----|-------------------------|---|---|------------------------------|---|---|--|---|---|-------------------------------------|---|---|----------------------------|---|---|----------------------|---|---|------------------|---|---|--------------------------------------|---|---|
| coronary artery bypass graft   | C                            |    |                   |   |      |   |       |   |  |  |     |    |                         |   |   |                              |   |   |  |   |   |                                     |   |   |                            |   |   |                      |   |   |                  |   |   |                                      |   |   |
| valve replacement  | V                            |    |                   |   |      |   |       |   |  |  |     |    |                         |   |   |                              |   |   |  |   |   |                                     |   |   |                            |   |   |                      |   |   |                  |   |   |                                      |   |   |
| PCTA   | A                            |    |                   |   |      |   |       |   |  |  |     |    |                         |   |   |                              |   |   |  |   |   |                                     |   |   |                            |   |   |                      |   |   |                  |   |   |                                      |   |   |
| Other  | O                            |    |                   |   |      |   |       |   |  |  |     |    |                         |   |   |                              |   |   |  |   |   |                                     |   |   |                            |   |   |                      |   |   |                  |   |   |                                      |   |   |
|  | 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                            | R  |                   |   |      |   |       |   |  |  |     |    |                         |   |   |                              |   |   |  |   |   |                                     |   |   |                            |   |   |                      |   |   |                  |   |   |                                      |   |   |
| 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

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

- 27.1. EF Percentage.....

- 27.2. Date Obtained:

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



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 H

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 H

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) <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px;"> </td><td style="width: 20px;"> </td><td style="width: 20px;"> </td><td style="width: 20px;"> </td></tr></table> |                              |  |  |  | b) <table style="display: inline-table;"><tr><td style="width: 20px;">Q</td></tr><tr><td style="width: 20px;">B</td></tr></table> | Q | B |
|           |  |                              |  |  |  |   |   |   |
| Q         |  |                              |  |  |  |   |   |   |
| B         |  |                              |  |  |  |   |   |   |
| 5.0 mg    | c) <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px;"> </td><td style="width: 20px;"> </td><td style="width: 20px;"> </td><td style="width: 20px;"> </td></tr></table> |                              |  |  |  | d) <table style="display: inline-table;"><tr><td style="width: 20px;">Q</td></tr><tr><td style="width: 20px;">B</td></tr></table> | Q | B |
|           |  |                              |  |  |  |   |   |   |
| Q         |  |                              |  |  |  |   |   |   |
| B         |  |                              |  |  |  |   |   |   |
| 10.0 mg   | e) <table border="1" style="display: inline-table; border-collapse: collapse;"><tr><td style="width: 20px;"> </td><td style="width: 20px;"> </td><td style="width: 20px;"> </td><td style="width: 20px;"> </td></tr></table> |                              |  |  |  | f) <table style="display: inline-table;"><tr><td style="width: 20px;">Q</td></tr><tr><td style="width: 20px;">B</td></tr></table> | Q | B |
|           |  |                              |  |  |  |   |   |   |
| Q         |  |                              |  |  |  |   |   |   |
| B         |  |                              |  |  |  |   |   |   |

43. Date of next scheduled visit:

|       |     |      |  |  |  |
|-------|-----|------|--|--|--|
|       |     |      |  |  |  |
| Month | Day | Year |  |  |  |