

SOLVD

MEDICATION TOLERANCE VISIT FORM

VERSION B / 9-1-1986

TEMP ID:

FORM: S M T VERSION: B VISIT: 2

INSTRUCTIONS:

This form is to be used only at Visit 2, the SOLVD Medication Tolerance Visit. 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 MEDICATION TOLERANCE VISIT FORM (screen 1 of 5) (SMT page 1 of 3)

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 1: / /
Month Day Year

b) Number of days since Visit 1.....

c) Number of pills dispensed at Visit 1.

d) Number of pills returned today.....

e) Adherence..... %

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

B. PHYSICAL EXAMINATION

Blood Pressure (sitting)

1. Systolic..... mm Hg

2. Diastolic..... mm Hg

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

C. EXCLUSION CRITERIA

5. Has the participant taken 75% or more of the prescribed medication (with at least some taken in the last 2 days)?.....Yes Y
 No N

NOTE: If the participant has not taken 75% or more of the medication and is willing to repeat Visit 2, do not complete this form. Reissue the Visit 1 medication and reschedule the participant for Visit 2. Only 2 attempts at Visit 2 are allowed. Only 1 form will be accepted for this visit.

5a. Was the participant given a second chance for medication tolerance?.....Yes Y
 No N

NOTE: If the participant is continuing the use of a non-ACE vasodilator, please consider discontinuing use unless the indication is clear.

6.1. Is the participant discontinuing the use of all non-ACE vasodilators?.....Yes Y
 No N

If Yes, go to Question 7.1.

6.2. If No (continuing), specify the indication:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

7.1. Has the participant tolerated the test medication so far?.....Yes Y
 No N

If Yes, go to Question 7.7a.

If No, indicate the reason(s) below:

Yes No
 7.2. Symptomatic hypotension..... Y N
 7.3. Altered Taste..... Y N
 7.4. Skin rash..... Y N
 7.5. Did not take medication..... Y N
 7.6. Other..... Y N

If No (Other), go to Question 7.7.

If Yes (Other), specify:

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

7.7. Is the participant willing to continue on medication despite side effects?.....Yes Y
 No N

7.7a. Does the participant still meet the inclusion criteria?.....Yes Y
 No N

If Yes, go to Question B. on page 3.

7.7b. If No, enter the number of the most important inclusion criterion not met.....

NOTE: Enter the number (01-26) of the inclusion criterion from the SOLVD Eligibility Form. The number used is the decimal portion of Question 15. on the SOLVD Eligibility Visit Form.
 e. g.: Cancer = 18 since Cancer is Question 15.18 on the SOLVD Eligibility Visit Form.

D. INITIALS OF PERSON COMPLETING THIS FORM

B. Initials.....

E. TRIAL SUITABILITY

9. Is the participant still eligible to continue in SOLVD?.....Yes Y
 No N

If Yes (the participant is still eligible to continue in SOLVD), continue with section F. LABORATORY DATA, Question 10.

If No, EXIT THE FORM.

F. LABORATORY DATA

10. Hematocrit (HCT)..... %

11.1. Total White Blood Count (WBC x1000).....

11.2. Percent Neutrophils.....

11.3. Percent Lymphocytes.....

12. Sodium (Na)..... . meq/l

13. Potassium (K)..... meq/l

14. Blood Urea Nitrogen (BUN).. mg/dl

15. Creatinine..... mg/dl

16a. Proteinuria.....negative 0
 trace or + 1
 ++ 2
 +++ 3
 ++++ 4

G. PARTICIPANT SUITABILITY

17.1. Is the participant still suitable to continue?.....Yes Y
 No N

If Yes, go to Question 17.3.

17.2. If No, specify reason(s):

17.3. If Yes, enter the scheduled date of Baseline Visit 3 (Randomization):

/ /

Month Day Year

OPTIONAL DATA FOR LOCAL CLINIC USE ONLY

a) Number of pills dispensed at this visit.....

1st attempt 2nd attempt