FOLLOW-UP FORM

Randomization Number
__ __ __ / __ __ __ __

Local Center Name _____

PRINT Patient Name _____
Last First M.I.

Date of Follow-Up Visit Mo __ __ Day __ __ Yr __ __

CIRCLE CLOSEST VISIT (MONTH): 01* 04 08 12* 16 20 24 28 32 36 40 44 48 52 56 60

NUMBER:

(*Please draw Digoxin blood level at this visit if instructed by the Data Coordinating Center.)

1. DID PATIENT COME TO THIS SCHEDULED VISIT? (1=Yes, Go to Q.4; 0=No, Go to Q.2) ..... _Q1_

2. IF PATIENT DID NOT COME TO VISIT, INDICATE REASON ..... _Q2_
   1=Missed visit (visit should be rescheduled)
   2=Refuses further participation (try to keep the patient in the study, at least by telephone contact)
   3=Lost to follow-up (contact private physician, relative, or friend)
   4=Died (complete Q. 3)

   If the patient has not come to the visit, please make every effort to contact the patient and complete another copy of this form at least by telephone conversation.

3. IF PATIENT DIED: (Please call 1-800-336-2309 to inform the Data Coordinating Center of the date of death if there is a delay of greater than 4 weeks in obtaining the information in Q. 3B.)

   A. DATE OF DEATH ..... Mo Q3A_MO Day Q3A_DA Yr Q3A_YR

   B. PRIMARY CAUSE OF DEATH Q3B
   1=Presumed arrhythmic and no evidence of worsening CHF
   2=Progressive heart failure (include patients with worsening CHF, even if the terminal event is an arrhythmia)
   3=Other cardiac, specify _____
   4=Stroke
   5=Embolism, specify _____
   6=Other vascular, specify _____
   7=Noncardiac, nonvascular, specify _____
   8=Unknown

4. SINCE LAST VISIT, HOW MANY TIMES HAS THE PATIENT BEEN HOSPITALIZED? Q4
   (If none, enter "0")
   (Hospitalization, for study purposes, is defined as admission to hospital for at least 24 hours.)

PLEASE COMPLETE A SEPARATE EVENT FORM FOR EACH HOSPITALIZATION.

5. CURRENT NYHA FUNCTIONAL CLASS (use codes below) Q5
   1 = Class I (Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue or dyspnea).
   2 = Class II (Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity causes fatigue or dyspnea).
   3 = Class III (Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue or dyspnea).
   4 = Class IV ((Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency are present even at rest. If any physical activity is undertaken, symptoms are increased.)

6. SINCE LAST VISIT, HAS THE DOSE OF DIURETICS, ACE-INHIBITORS OR ANY OTHER NON-TRIAL THERAPY BEEN INCREASED FOR WORSENING HEART FAILURE? (1=Yes, 0=No) .. Q6

A. IF YES, HOW MANY TIMES HAS THE PATIENT REQUIRED ANY OF THE FOLLOWING: (If none, enter "0")

1) unscheduled office visit(s) Q6A1

2) emergency room visit(s) Q6A2

3) hospitalization(s) for less than 24 hours Q6A3

(Code: 1=Yes 0=No)

7. CURRENT ACE INHIBITOR USE Q7
8. NITRATES (ORAL OR PASTE) Q8
9. HYDRALAZINE Q9
10. OTHER VASODILATORS, SPECIFY _____Q10_SPEC_____ Q10
11. POTASSIUM SPARING DIURETICS Q11
12. OTHER DIURETICS Q12
12A. POTASSIUM SUPPLEMENT Q12A
13. HOW MANY STUDY TABLETS (D-995) HAVE BEEN RETURNED? Q13_MLS mls (cylinder) OR Q13_TABS tabs (tablet count)
14. WHAT PROPORTION OF STUDY TABLETS DOES THE PATIENT REPORT HAVING TAKEN SINCE LAST VISIT? Q14

1=None/few (<20%)
2=Some (20-80%)
3=Most/all (>80%)

} ACTION: Please encourage patient to take tablets regularly if possible.

15. IS THE PATIENT CONTINUING STUDY DRUG? (1=Yes, 0=No) Q15

IF YES:

A. CODE DOSE PRESCRIBED AT THIS VISIT (For doses of 0.125 or 0.25 mg give one bottle; for 0.375 or 0.5 mg give 2 bottles of study drug.) Q15A

1=0.125 mg/day (1 tab/day) 3=0.375 mg/day (3 tabs/day)
2=0.25 mg/day (2 tabs/day) 4=0.50 mg/day (4 tabs/day)

B. INDICATE NUMBER OF BOTTLES DISPENSED AT THIS VISIT (270 tablets/bottle) Q15B

IF NO:

C. CODE REASON FOR STOPPING Q15C

1=Side effects, specify _____Q15C_SPE_____
2=Renal insufficiency
3=Prescription of open label digoxin due to CHF
4=Prescription of open label digoxin due to atrial fibrillation/flutter
5=Other, specify _____

If patient has stopped study medication, please try to restart at a lower dose. If not possible, the patient should remain in the study until follow-up is completed.

16. HAS DOSE BEEN CHANGED SINCE THE LAST VISIT? (1=Yes, 0=No) Q16

A. IF YES, SPECIFY REASON Q16A

1=Renal insufficiency
2=Side effects, specify _____Q16A_SPE_____
3=Other, specify _____

17. HAS PATIENT'S ADDRESS CHANGED? (1=Yes, 0=No) .....

A. IF YES, SPECIFY NEW ADDRESS BELOW:

_____

_____

TELEPHONE: AREA CODE: _____ NUMBER: _____

18. DATE OF NEXT VISIT ..... Mo __ __ Day __ __ Yr __ __
19. LAST NAME AND FIRST INITIAL OF INDIVIDUAL COMPLETING THIS FORM (IN CAPITALS) ..... _____ (Last) _____ (First Initial)

Signature _____

PLEASE RETURN FORM TO DATA COORDINATING CENTER AT PERRY POINT.