33263

AFFIRM

Baseline

Fax to: (800) 547-0463

Instructions: This form should be initiated at the time of randomization. For best results, use a black felt tip pen with a fine point. Do not use pencil or light-colored pens. Whenever numerical information is required, enter numbers with the last digit in the rightmost box. Please print numeric or letter characters clearly, in upper-case block format, in the center of each box (avoid touching the lines). When a no/yes or categorical response is required, completely fill the correct bubble ●, or put an x through it ⊗ (please do not check the bubble).

1. Date of interview:

Month / Day / Year

(On or after date of randomization)

Days01

Affix Patient ID # Here

Print Acrostic Here

2. Was congestive heart failure present when the patient was last in regular sinus rhythm prior to the qualifying arrhythmia?

○ No *0* ○ Yes *1* ○ Unknown

PrvCHFP

3. Was angina pectoris present when the patient was last in regular sinus rhythm prior to the qualifying arrhythmia?

○ No *0* ○ Yes *1* ○ Unknown

PrvAngP

4. History at any time prior to randomization:

	No 0	Yes 1			No 0	Yes 1	
CAD01	○	○	Coronary artery disease		○	○	Intracranial bleed
Angina01	○	○	Angina pectoris		○	○	Systemic embolism
MI01	○	○	Myocardial infarction	*Periph01*	○	○	Peripheral vascular disease
CHF01	○	○	Congestive heart failure		○	○	Carotid artery disease
Hypten01	○	○	Hypertension		○	○	Hemorrhage or coagulopathy
CMYop01	○	○	Cardiomyopathy	*Diabts01*	○	○	Diabetes
Valv01	○	○	Valvular heart disease	*Hepat01*	○	○	Hepatic or renal disease
Congen01	○	○	Congenital heart disease	*Pulmon01*	○	○	Pulmonary disease
Brady01	○	○	Symptomatic bradycardia or AV block	*Smoker01*	○	○	Smoking (within 2 years)
	○	○	Resuscitated cardiac arrest		○	○	Thyroid disease
Stroke01	○	○	Stroke or TIA				

For CTC use only:

Date of interview:

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5. Cardiac procedures at any time prior to randomization:

	No 0	Yes 1	
CABG01	○	○	CABG
Interv01	○	○	Interventional procedures (PTCA, atherectomy, stent, etc.)
Pacemk01	○	○	Pacemaker implantation ⇒ Specify type: *(Mark one only.)* ○ Atrial ○ Ventricular ○ Dual chamber
Proco01	○	○	Thrombolytic therapy
	○	○	Other (includes ablation) ⇒ Specify:

(Thrombolytic Therapy or Other)

6. Symptoms experienced during atrial fibrillation in the last six months (ask patient about each symptom):

	No 0	Yes 1		No 0	Yes 1		
ChPain01	○	○	Chest pain	○	○	Fatigue	Fatig01
Diaph01	○	○	Diaphoresis	○	○	Nausea	
Diures01	○	○	Diuresis	○	○	Orthopnea	Orthop01
Dizzy01	○	○	Dizziness or lightheadedness	○	○	Palpitations	Palp01
Dysp01	○	○	Dyspnea	○	○	Panic	Panic01
Edema01	○	○	Edema	○	○	PND	PND01
Fast01	○	○	Fast heart rate	○	○	Syncope	Sync01
SympO0	○	○	Other ⇒ Specify:				

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Date of interview:

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7. Was this the patient's first episode of atrial fibrillation?

First01
- ○ 0 Yes
- ○ 1 No ⇒ Specify frequency of symptomatic episodes of atrial fibrillation: *(Mark one only.)*

Freq01
- ○ 5 Very frequent episodes, more than once a day
- ○ 4 Frequent, daily to more than once a week
- ○ 3 Occasional, weekly to more than once a month
- ○ 2 Infrequent, monthly to two in six months
- ○ 1 Very infrequent, one in six months
- ○ 1 Asymptomatic

8. Duration of qualifying episode of atrial fibrillation: *(Mark one duration.)*

○ 0 < 6 hours ⇒ **Complete the following:**

Was patient cardioverted prior to 6 hours?

○ Yes ⇒ Go to Question 9.

○ No ⇒ **Were prior episodes documented by ECG?**

○ Yes ⇒ Go to Question 9.

○ No ⇒ **Were episodes documented by a physician?**

○ Yes ⇒ Go to Question 9.

○ No ⇒ **Were episodes documented by patient history?**

○ Yes

○ No

Durat01
- ○ 1 ≥ 6 hours but < 12 hours
- ○ 2 ≥ 12 hours but < 48 hours
- ○ 3 ≥ 2 days but < 30 days
- ○ 4 ≥ 30 days but ≤ 6 months
- ○ 4 > 6 months (with sinus rhythm subsequently maintained ≥ 24 hours)

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9. Maximum recorded ventricular rate of qualifying episode of atrial fibrillation (rhythm strip at least six seconds):

MaxVR01

10. Rhythm at time of randomization: *(Mark one only.)*

Rhythm

○ 1 Atrial fibrillation or flutter
○ 2 Sinus (normal, tachycardia, or bradycardia)
○ Other ⇒ Specify:

11. Predominant cardiac diagnosis: *(Mark one only.)*

Cause01

○ 1 Coronary artery disease (MI, angina, etc.)
○ 2 Dilated nonischemic cardiomyopathy
○ 3 Hypertension
○ 4 Valvular heart disease
○ 4 Other ⇒ Specify:
○ 0 None apparent

12. Height and weight: *BMI (Kg/m2)*

Height: inches or . meters

Weight: pounds or . kilograms

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Date of interview: ☐☐ / ☐☐ / ☐☐
Month Day Year

Affix Patient ID # Here
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13. Has patient had antiarrhythmic drug failures prior to randomization?

Fail01
○ 0 No
○ 1 Yes ⇒ Complete the following:

a. Total number of failures: ☐☐

b. Indicate all of the following drugs failed prior to randomization:

No	Yes		No	Yes	
○	○	Amiodarone	○	○	Procainamide
○	○	Disopyramide	○	○	Propafenone
○	○	Flecainide	○	○	Quinidine
○	○	Moricizine	○	○	Sotalol
○	○	Other antiarrhythmics ⇒ Specify:			

☐☐☐☐☐☐☐☐☐☐☐☐
☐☐☐☐☐☐☐☐☐☐☐☐

14. Antiplatelet/anticoagulant drugs taken prior to randomization:

	No 0	Yes 1	
Asprn01	○	○	Aspirin
Hepar01	○	○	Heparin
Warf01	○	○	Warfarin ⇒ If yes, complete the following:

INR01 a. Most recent INR: ☐☐.☐

Dwarf01 b. Duration of warfarin: ○ 1 < 12 weeks ⇒ Number of weeks: ☐☐
○ 2 ≥ 12 weeks

○ ○ Other ⇒ Specify: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

For CTC use only: ☐☐

Date of interview:

Month / Day / Year

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15. Medications not listed above taken within 6 months prior to randomization:

	No 0	Yes 1	
ACE01	○	○	Angiotensin/ACE inhibitor
	○	○	Beta adrenergic stimulants
BetaBl01	○	○	Beta blocker
			Calcium channel blockers:
Dilt01	○	○	Diltiazem
Verap01	○	○	Verapamil
CalcO01	○	○	Other
	○	○	Other cardiac medications ⇒ Specify:

	No 0	Yes 1	
Digox01	○	○	Digoxin
Diuret01	○	○	Diuretic
Estrog01	○	○	Estrogen/progesterone therapy
Lipid01	○	○	Lipid-lowering
Nitrat01	○	○	Nitrate
AntHyp01	○	○	Other antihypertensive
	○	○	Theophylline
	○	○	Thyroid replacement therapy

16. Was an echocardiogram obtained in the last year?

Echo01
- ○ 0 No
- ○ 1 Yes ⇒ Specify type(s):

No	Yes		
○	○	Transthoracic echocardiogram	⇒ Complete Transthoracic Echocardiogram form
○	○	Transesophageal echocardiogram	⇒ Complete Transesophageal Echocardiogram form

For CTC use only:

Date of interview:

__ __ / __ __ / __ __

Month Day Year

Affix Patient ID # Here

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Items 17-25 should be completed when the patient is stable after intended initial drug therapy has been started, but no later than 14 days after randomization. Only the first drug trial should be included. In items 21-25, the best status of the patient should be recorded.

17. Electrical or pharmacologic cardioversion since onset of qualifying episode of atrial fibrillation?

○ No ⇒ Go to Question 18.

Cardio01 *0*

○ Yes ⇒ Enter the total number of episodes and the number of successful episodes of cardioversion for the qualifying arrhythmia prior to randomization:

	Electrical	Pharmacologic	Used both
Total number of episodes:	__ __ *ElecT101*	__ __ *PharT101*	__ __ *BothT101*
Number of successful episodes:	__ __ *ElecS101*	__ __ *PharS101*	__ __ *BothS101*

1

⇒ Enter the total number of episodes and the number of successful episodes of cardioversion since randomization:

	Electrical	Pharmacologic	Used both
Total number of episodes:	__ __ *ElecT201*	__ __ *PharT201*	__ __ *BothT201*
Number of successful episodes:	__ __ *ElecS201*	__ __ *PharS201*	__ __ *BothS201*

⇒ If any episodes (either before or after randomization) were electrical or used both, was internal electrical cardioversion administered?

○ No ○ Yes

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__ __

Date of interview:

Month / Day / Year

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18. Hospitalization for qualifying episode of atrial fibrillation?

Hosp01

○ No 0

○ Yes 1 ⇒ Mark number of inpatient days for each:

Total days: DaysT01

Critical care: DaysC01

Non-critical care: DaysNC01

19. Has randomized treatment strategy been started?

○ No 0 ⇒ Specify reason:

○ Patient is randomized to rate control and demonstrates one of the following:

- Rate control without drugs at rest and during exercise or
- Normal sinus rhythm.

Start01

○ Other ⇒ Send letter from investigator describing circumstances.

⇒ Go to Question 21.

○ Yes 1 ⇒ Date of initiation of randomized treatment strategy:

Month / Day / Year

InitDy01

20. Which of the following drugs have been started or continued as the initial therapy after randomization?

	No 0	Yes 1		No 0	Yes 1		
InAmio01	○	○	Amiodarone	○	○	Moricizine	
InBeta01	○	○	Beta blocker	○	○	Procainamide	
InDigo01	○	○	Digoxin	○	○	Propafenone	
InDilt01	○	○	Diltiazem	○	○	Quinidine	
	○	○	Disopyramide	○	○	Sotalol	InSota01
	○	○	Flecainide	○	○	Verapamil	InVera01

InClassI - Class I drug (Disopyramide or Flecainide or Moricizine or Procainamide or Propafenone or Quinidine)

For CTC use only: (0=No, 1=Yes)

Date of interview:

☐☐ / ☐☐ / ☐☐

Month Day Year

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21. Current congestive heart failure status: (*Mark the NYHA classification for current functional capacity.*)

NYHC01 ○ 0 No CHF ○ 1 Class I ○ 2 Class II ○ 3 Class III ○ 4 Class IV

22. Current angina status: (*Mark the Canadian Cardiovascular Society classification for current angina status.*)

CHC01 ○ 0 No angina ○ 1 Class I ○ 2 Class II ○ 2 Class III ○ 2 Class IV

23. Current ventricular heart rate (apical rate for one minute): ☐☐☐

CurVR

24. Is the patient currently in atrial fibrillation or flutter?

CurAF01 ○ 0 No
○ 1 Yes ⇒ ○ Atrial fibrillation
○ Atrial flutter

25. Current blood pressure (systolic/diastolic): ☐☐☐ / ☐☐☐

BPsys01 *BPDias01*

Name of person completing this form _____

Please print

Date of assessment of items 21-25:

☐☐ / ☐☐ / ☐☐

Month Day Year

SignDy01

For CTC use only: ☐☐