SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: ☐ Baseline ☐ 4 month ☐ 12 month ☐ 24 month ☐ 36 month ☐ 48 month

A4. Date QOL instruments completed: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

A5. How were the questionnaires completed?

☐1 In-person

☐2 Mailed to subject

A6. Who completed the quality of life questionnaires?

☐1 The subject, without assistance

☐2 The subject, with assistance (e.g. administered/read by the study coordinator)

☐3 A proxy (e.g. spouse, relative, friend) on behalf of the subject

☐-8 Unknown

The KC Cardiomyopathy Questionnaire

The following questions refer to your **heart failure** and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1. **Heart failure** affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by **heart failure** (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks.

Please place an ☒ in one box on each line

Activity	Extremely Limited	Quite a bit Limited	Moderately Limited	Slightly Limited	Not at all Limited	Limited for other reasons or did not do the activity
Dressing yourself	☐	☐	☐	☐	☐	☐
Showering/Bathing	☐	☐	☐	☐	☐	☐
Walking 1 block on level ground	☐	☐	☐	☐	☐	☐
Doing yardwork, housework or carrying groceries	☐	☐	☐	☐	☐	☐
Climbing a flight of stairs without stopping	☐	☐	☐	☐	☐	☐
Hurrying or jogging (as if to catch a bus)	☐	☐	☐	☐	☐	☐

2. Compared with 2 weeks ago, have your symptoms of **heart failure** (shortness of breath, fatigue, or ankle swelling) changed?

My symptoms of **heart failure** have become...

Much worse	Slightly worse	Not changed	Slightly better	Much better	I've had no symptoms over the last 2 weeks
☐	☐	☐	☐	☐	☐

3. Over the past 2 weeks, how many times did you have **swelling** in your feet, ankles or legs when you woke up in the morning?

Every morning	3 or more times per week, but not every day	1-2 times a week	Less than once a week	Never over the past 2 weeks
☐	☐	☐	☐	☐

4. Over the past 2 weeks, how much has **swelling** in your feet, ankles or legs bothered you?

It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no swelling**
☐	☐	☐	☐	☐	☐

5. Over the past 2 weeks, on average, how many times has **fatigue** limited your ability to do what you want?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 2 weeks
☐	☐	☐	☐	☐	☐	☐

6. Over the past 2 weeks, how much has your **fatigue** bothered you?

It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no fatigue**
☐	☐	☐	☐	☐	☐

7. Over the past 2 weeks, on average, how many times has **shortness of breath** limited your ability to do what you wanted?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 2 weeks
☐	☐	☐	☐	☐	☐	☐

8. Over the past 2 weeks, how much has your **shortness of breath** bothered you?

It has been...

Extremely bothersome	**Quite a bit** bothersome	**Moderately** bothersome	**Slightly** bothersome	**Not at all** bothersome	I've had **no shortness of breath**
☐	☐	☐	☐	☐	☐

9. Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of **shortness of breath**?

Every night	3 or more times a week, but not every day	1-2 times a week	Less than once a week	Never over the past 2 weeks
☐	☐	☐	☐	☐

10. **Heart failure** symptoms can worsen for a number of reasons. How sure are you that you know what to do, or whom to call, if your **heart failure** gets worse?

Not at all sure	**Not very** sure	**Somewhat** sure	**Mostly** sure	**Completely** sure
☐	☐	☐	☐	☐

11. How well do you understand what things you are able to do to keep your **heart failure** symptoms from getting worse? (for example, weighing yourself, eating a low salt diet etc.)

Do not understand at all	Do not understand very well	Somewhat understand	Mostly understand	Completely understand
☐	☐	☐	☐	☐

12. Over the past 2 weeks, how much has your **heart failure** limited your enjoyment of life?

It has **extremely** limited my enjoyment of life	It has limited my enjoyment of life **quite a bit**	It has **moderately** limited my enjoyment of life	It has **slightly** limited my enjoyment of life	It has **not limited** my enjoyment of life at all
☐	☐	☐	☐	☐

13. If you had to spend the rest of your life with your **heart failure** the way it is right now, how would you feel about this?

Not at all satisfied	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied
☐	☐	☐	☐	☐

14. Over the past 2 weeks, how often have you felt discouraged or down in the dumps because of your **heart failure**?

I felt that way **all of the time**	I felt that way **most of the time**	I **occasionally** felt that way	I **rarely** felt that way	I **never** felt that way
☐	☐	☐	☐	☐

15. How much does your **heart failure** affect your lifestyle? Please indicate how your **heart failure** may have limited your participation in the following activities over the past 2 weeks.

Please place an [X] in one box on each line

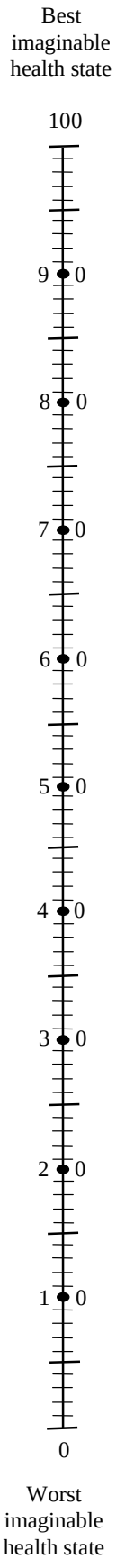
Activity	Severely limited	Limited quite a bit	Moderately limited	Slightly limited	Did not limit at all	Does not apply or did not do for other reasons
Hobbies, recreational activities	☐	☐	☐	☐	☐	☐
Working or doing household chores	☐	☐	☐	☐	☐	☐
Visiting family or friends out of your home	☐	☐	☐	☐	☐	☐
Intimate relationships with loved ones	☐	☐	☐	☐	☐	☐

Visual Analog Scale

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own health state today



Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___ Subject Initials: ___ ___ ___

Date completed: __ __ - __ __ __ - __ __ __ __ (D D - M M M - Y Y Y Y) Visit: ___ ___ ___ ___

PHQ9P

PATIENT HEALTH QUESTIONNAIRE-9

72883

THIS SECTION FOR USE BY STUDY PERSONNEL ONLY.

Were data collected? **No** ☐ *(provide reason in comments)*

If **Yes**, data collected on visit date ☐ **or** specify date: _____ (DD-Mon-YYYY)

Comments:

Only the patient (subject) should enter information onto this questionnaire.

Over the last 2 weeks, how often have you been bothered by any of the following problems?	**Not at all**	**Several days**	**More than half the days**	**Nearly every day**
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

SCORING FOR USE BY STUDY PERSONNEL ONLY

0 + _____ + _____ + _____

=Total Score: _____

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all	**Somewhat difficult**	**Very difficult**	**Extremely difficult**
☐	☐	☐	☐

Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc.

EPI0905.PHQ9P

I confirm this information is accurate.	Patient's/Subject's initials:	Date:

Overall Treatment Evaluation - CHF

We would like to find out if there are any changes in the way you have been feeling since treatment started, i.e., 14 months ago.

Since treatment started, has there been any change in your ACTIVITY LIMITATION, SYMPTOMS AND/OR FEELINGS related to your heart condition? Please indicate if there has been any change by checking **ONE** of the three boxes below ***(Better/About the same/Worse):***

☐ Better ☐ About the same ☐ Worse

If you have checked the box ABOUT THE SAME, please stop here

If you have checked the box BETTER:
How much BETTER would you say Your ACTIVITY LIMITATION, SYMPTOMS AND/OR FEELINGS have been since treatment started? Please choose ONE of the options below:

- ☐ Almost the same, hardly better at all
- ☐ A little better
- ☐ Somewhat better
- ☐ Moderately better
- ☐ A good deal better
- ☐ A great deal better
- ☐ A very great deal better

If you have checked the box WORSE:
How much WORSE would you say Your ACTIVITY LIMITATION, SYMPTOMS AND/OR FEELINGS have been since treatment started? Please choose ONE of the options below:

- ☐ Almost the same, hardly worse at all
- ☐ A little worse
- ☐ Somewhat worse
- ☐ Moderately worse
- ☐ A good deal worse
- ☐ A great deal worse
- ☐ A very great worse

Overall Treatment Effect - CHF, continued

Answer the following question whether or not you answered BETTER or WORSE and what your response was. Note if you have improved, the change will be Important since you likely will be able to carry out your responsibilities with greater ease and comfort compared to before the study. If on the other hand you are worse, then you will have more difficulty carrying out your responsibilities; this will also be important for you as you have more difficulty with your activities.

Is this change (BETTER/WORSE) important to you in carrying out your daily activities?

- ☐ Not important
- ☐ Slightly important
- ☐ Somewhat Important
- ☐ Moderately important
- ☐ Important
- ☐ Very Important
- ☐ Extremely Important

THANKS FOR YOUR COOPERATION!

Consent Confirmation

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: BASELINE

SECTION B: TRIAL CONSENT

		YES	NO	
B1.	Has the subject signed a consent form to participate in the TOPCAT trial?	☐1	☐0	**(END)**
	a. Date consent signed:	__ __ - __ __ __ - __ __ __ __		
		D D - M M M - Y Y Y Y		

SECTION C: REPOSITORY CONSENT

		YES	NO	
C1.	Has the subject signed a consent form to participate in the repository sub-study?	☐1	☐0	**(END)**
	a. Date consent signed:	__ __ - __ __ __ - __ __ __ __		
		D D / M M M / Y Y Y Y		
C2.	Has the subject consented to blood specimen collection and analysis?	☐1	☐0	
C3.	Has the subject consented to urine specimen collection and analysis?	☐1	☐0	
C4.	Has the subject consented to a DNA sample collection and analysis?	☐1	☐0	

Consent Confirmation

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit:
☐ Baseline ☐ 4 week ☐ 8 week ☐ 4 month ☐ 8 month
☐ 12 month ☐ 18 month ☐ 24 month ☐ 30 month ☐ 36 month
☐ 42 month ☐ 48 month ☐ 54 month

SECTION B: TRIAL CONSENT

		YES	NO	
B1.	Has the subject signed a consent form to participate in the TOPCAT trial?	☐1	☐0	**(END)**
	a. Date consent signed: __ __ - __ __ __ - __ __ __ __ (D D - M M M - Y Y Y Y)			

If your site's IRB (or Central IRB) has approved a consent form which includes echocardiogram release, please complete the following question:

		YES	NO
b.	Has the subject consented to sending the echocardiogram for QC purposes?	☐1	☐0

SECTION C: REPOSITORY CONSENT

		YES	NO	
C1.	Has the subject signed a consent form to participate in the repository sub-study?	☐1	☐0	**(END)**
	a. Date consent signed: __ __ - __ __ __ - __ __ __ __ (D D / M M M / Y Y Y Y)			
C2.	Has the subject consented to blood specimen collection and analysis?	☐1	☐0	
C3.	Has the subject consented to urine specimen collection and analysis?	☐1	☐0	
C4.	Has the subject consented to a DNA sample collection and analysis?	☐1	☐0	

Consent Confirmation

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit:
☐ Baseline ☐ 4 week ☐ 8 week ☐ 4 month ☐ 8 month
☐ 12 month ☐ 18 month ☐ 24 month ☐ 30 month ☐ 36 month
☐ 42 month ☐ 48 month ☐ 54 month

SECTION B: TRIAL CONSENT

		YES	NO	
B1.	Has the subject signed a consent form to participate in the TOPCAT trial?	☐1	☐0	**(END)**

a. Date consent signed: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

If your site's IRB (or Central IRB) has approved a consent form which includes echocardiogram release, please complete the following question:

		YES	NO
b.	Has the subject consented to sending the echocardiogram for QC purposes?	☐1	☐0

SECTION C: REPOSITORY CONSENT

Please answer questions regarding the Repository at the Baseline visit ONLY.

		YES	NO	
C1.	Has the subject signed a consent form to participate in the repository sub-study?	☐1	☐0	**(END)**

a. Date consent signed: __ __ - __ __ __ - __ __ __ __
D D / M M M / Y Y Y Y

		YES	NO
C2.	Has the subject consented to blood and urine specimen collection and analysis?	☐1	☐0

SECTION C: REPOSITORY CONSENT (continued)

		YES	NO	
C3.	Has the subject consented to DNA specimen collection and analysis?	☐1	☐0	**(END)**

a. Diseases to be studied:

☐1 To be studied for genes related to any disease, health condition or risk factors.

☐2 To be studied ONLY for genes related to heart disease, stroke, kidney diseases, other cardiovascular diseases, or risk factors associated with these diseases.

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: BASELINE

SECTION B: INCLUSION CRITERIA

		YES	NO
B1.	Male or female; Age 50 years or older:	☐1	☐0
B2.	Heart failure as defined in Table 1. One symptom must be present at the time of screening and one sign must be present in the last 12 months:	☐1	☐0

TABLE 1. Criteria for Diagnosing Heart Failure

SYMPTOMS (at least one must be present at the time of screening)	SIGNS (at least one in last 12 mo.)
• Paroxysmal nocturnal dyspnea	• Any rales post cough
• Orthopnea	• Jugular venous pressure (JVP) ≥ 10 cm H_2O
• Dyspnea on mild or moderate exertion	• Lower extremity edema
	• Chest x-ray demonstrating pleural effusion, pulmonary congestion, or cardiomegaly

B3.	Left ventricular ejection fraction (ideally obtained by echocardiography, although radionuclide ventriculography and angiography are acceptable) ≥ 45% (per local reading). The ejection fraction must have been obtained within 6 months prior to randomization and after any MI or other event that would affect ejection fraction:	☐1	☐0
B4.	Controlled systolic BP, defined as a target systolic BP < 140 mm Hg. Subjects with BP up to and including 160 mm Hg are eligible for enrollment if on 3 or more medications to control BP:	☐1	☐0
B5.	Serum potassium < 5.0 mmol/L prior to randomization:	☐1	☐0
B6a.	At least one hospital admission in the last 12 months for which heart failure was a major component of the hospitalization. Transient heart failure in the context of myocardial infarction (MI) does not qualify:	☐1	☐0
	OR		
B6b.	Brain natriuretic peptide (BNP) in the last 30 days ≥ 100 pg/ml or N-terminal pro-BNP ≥ 360 pg/ml and not explained by another disease entity:	☐1	☐0

SECTION B: INCLUSION CRITERIA (continued)

		YES	NO	N/A
B7.	Women of child-bearing potential must have a negative serum/urine pregnancy test within 72 hours prior to randomization, must not be lactating, and must agree to use an effective method of contraception during the entire course of study participation:	☐1	☐0	☐-1
B8.	Willing to comply with scheduled monitoring visits, as outlined in Table 2 of the protocol:	☐1	☐0	
B9.	Informed consent form signed by the subject:	☐1	☐0	

SECTION C: EXCLUSION CRITERIA

		YES	NO
C1.	Severe systemic illness with life expectancy judged less than three years:	☐1	☐0
C2.	Chronic pulmonary disease requiring home O_2, oral steroid therapy or hospitalization for exacerbation within 12 months, or significant chronic pulmonary disease in the opinion of the investigator:	☐1	☐0
C3.	Known infiltrative or hypertrophic obstructive cardiomyopathy or known pericardial constriction:	☐1	☐0
C4.	Primary hemodynamically significant uncorrected valvular heart disease, obstructive or regurgitant, or any valvular disease expected to lead to surgery during the trial:	☐1	☐0
C5.	Atrial fibrillation with a resting heart rate > 90 bpm:	☐1	☐0
C6.	Myocardial infarction in past 90 days:	☐1	☐0
C7.	Coronary artery bypass graft surgery in past 90 days:	☐1	☐0
C8.	Percutaneous coronary intervention in past 30 days:	☐1	☐0
C9.	Heart transplant recipient:	☐1	☐0
C10.	Currently implanted left ventricular assist device:	☐1	☐0
C11.	Stroke in past 90 days:	☐1	☐0

SECTION C: EXCLUSION CRITERIA (continued)

		YES	NO
C12.	Systolic blood pressure (SBP) > 160 mm Hg:	☐1	☐0
C13.	Known orthostatic hypotension:	☐1	☐0
C14.	Gastrointestinal disorder that could interfere with study drug absorption:	☐1	☐0
C15.	Use of any aldosterone antagonist or potassium sparing medication in last 7 days:	☐1	☐0
C16.	Known intolerance to aldosterone antagonists:	☐1	☐0
C17.	Current lithium use:	☐1	☐0
C18.	Current participation (including prior 30 days) in any other therapeutic trial:	☐1	☐0
C19.	Any condition that, in the opinion of the investigator, may prevent the subject from adhering to the trial protocol:	☐1	☐0
C20.	History of hyperkalemia (serum potassium ≥ 5.5 mmol/L) in the past six months or serum potassium ≥ 5.0 mmol/L within the past two weeks:	☐1	☐0
C21.	Severe renal dysfunction, defined as an estimated glomerular filtration rate (GFR) < 30 ml/min (per the Modification of Diet in Renal Disease (MDRD) 4-component study equation). Subjects with serum creatinine ≥ 2.5 mg/dl are also excluded even if their GFR is ≥ 30 ml/min:	☐1	☐0
C22.	Known chronic hepatic disease, defined as aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels > 3.0 times the upper limit of normal as read at the local lab:	☐1	☐0

SECTION D: ELIGIBILITY STATUS

D1. Are all inclusion criteria questions answered YES? ☐1 YES ☐0 NO

D2. Are all exclusion criteria questions answered NO? ☐1 YES ☐0 NO

D3. Date eligibility determined: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

D4. Subject status on this date: ☐1 INPATIENT ☐2 OUTPATIENT

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: BASELINE

SECTION B: INCLUSION CRITERIA

		YES	NO
B1.	Male or female; Age 50 years or older:	☐1	☐0
B2.	Heart failure as defined in Table 1. One symptom must be present at the time of screening and one sign must be present in the last 12 months:	☐1	☐0
B3.	Left ventricular ejection fraction (ideally obtained by echocardiography, although radionuclide ventriculography and angiography are acceptable) ≥ 45% (per local reading). The ejection fraction must have been obtained within 6 months prior to randomization and after any MI or other event that would affect ejection fraction:	☐1	☐0
B4.	Controlled systolic BP, defined as a target systolic BP < 140 mm Hg. Subjects with BP up to and including 160 mm Hg are eligible for enrollment if on 3 or more medications to control BP:	☐1	☐0
B5.	Serum potassium < 5.0 mmol/L prior to randomization:	☐1	☐0
B6a.	At least one hospital admission in the last 12 months for which heart failure was a major component of the hospitalization. Transient heart failure in the context of myocardial infarction (MI) does not qualify:	☐1	☐0
	OR		
B6b.	Brain natriuretic peptide (BNP) in the last 30 days ≥ 100 pg/ml or N-terminal pro-BNP ≥ 360 pg/ml and not explained by another disease entity:	☐1	☐0

TABLE 1. Criteria for Diagnosing Heart Failure

SYMPTOMS (at least one must be present at the time of screening)	SIGNS (at least one in last 12 mo.)
• Paroxysmal nocturnal dyspnea	• Any rales post cough
• Orthopnea	• Jugular venous pressure (JVP) ≥ 10 cm H_2O
• Dyspnea on mild or moderate exertion	• Lower extremity edema
	• Chest x-ray demonstrating pleural effusion, pulmonary congestion, or cardiomegaly

SECTION B: INCLUSION CRITERIA (continued)

		YES	NO	N/A
B7.	Women of child-bearing potential must have a negative serum/urine pregnancy test within 72 hours prior to randomization, must not be lactating, and must agree to use an effective method of contraception during the entire course of study participation:	☐1	☐0	☐-1
B8.	Willing to comply with scheduled monitoring visits, as outlined in Table 2 of the protocol:	☐1	☐0	
B9.	Informed consent form signed by the subject:	☐1	☐0	

SECTION C: EXCLUSION CRITERIA

		YES	NO
C1.	Severe systemic illness with life expectancy judged less than three years:	☐1	☐0
C2.	Chronic pulmonary disease requiring home O_2, oral steroid therapy or hospitalization for exacerbation within 12 months, or significant chronic pulmonary disease in the opinion of the investigator:	☐1	☐0
C3.	Known infiltrative or hypertrophic obstructive cardiomyopathy or known pericardial constriction:	☐1	☐0
C4.	Primary hemodynamically significant uncorrected valvular heart disease, obstructive or regurgitant, or any valvular disease expected to lead to surgery during the trial:	☐1	☐0
C5.	Atrial fibrillation with a resting heart rate > 90 bpm:	☐1	☐0
C6.	Myocardial infarction in past 90 days:	☐1	☐0
C7.	Coronary artery bypass graft surgery in past 90 days:	☐1	☐0
C8.	Percutaneous coronary intervention in past 30 days:	☐1	☐0
C9.	Heart transplant recipient:	☐1	☐0
C10.	Currently implanted left ventricular assist device:	☐1	☐0
C11.	Stroke in past 90 days:	☐1	☐0

SECTION C: EXCLUSION CRITERIA (continued)

		YES	NO
C12.	Systolic blood pressure (SBP) > 160 mm Hg:	☐1	☐0
C13.	Known orthostatic hypotension:	☐1	☐0
C14.	Gastrointestinal disorder that could interfere with study drug absorption:	☐1	☐0
C15.	Use of any aldosterone antagonist or potassium sparing medication in last 7 days:	☐1	☐0
C16.	Known intolerance to aldosterone antagonists:	☐1	☐0
C17.	Current lithium use:	☐1	☐0
C18.	Current participation (including prior 30 days) in any other therapeutic trial:	☐1	☐0
C19.	Any condition that, in the opinion of the investigator, may prevent the subject from adhering to the trial protocol:	☐1	☐0
C20.	History of hyperkalemia (serum potassium ≥ 5.5 mmol/L) in the past six months or serum potassium ≥ 5.0 mmol/L within the past two weeks:	☐1	☐0
C21.	Severe renal dysfunction, defined as an estimated glomerular filtration rate (GFR) < 30 ml/min (per the Modification of Diet in Renal Disease (MDRD) 4-component study equation). Subjects with serum creatinine ≥ 2.5 mg/dl are also excluded even if their GFR is ≥ 30 ml/min:	☐1	☐0
C22.	Known chronic hepatic disease, defined as aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels > 3.0 times the upper limit of normal as read at the local lab:	☐1	☐0

SECTION D: ELIGIBILITY STATUS

D1.	Are all inclusion criteria questions answered YES?	☐1 YES	☐0 NO
D2.	Are all exclusion criteria questions answered NO?	☐1 YES	☐0 NO
D3.	Date eligibility determined:	__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y	
D4.	Subject status on this date:	☐1 INPATIENT	☐2 OUTPATIENT

SECTION D: ELIGIBILITY STATUS (continued)

D5. Has the subject used any aldosterone antagonist or potassium sparing medication in 30 days prior to the date that eligibility was determined? ☐1 YES ☐0 NO

	a. Aldosterone Antagonist / Potassium Sparing Medication	b. Date last used (DD-MMM-YYYY)
1.		__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y
2.		__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y
3.		__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y
4.		__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y
5.		__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: BASELINE

SECTION B: INCLUSION CRITERIA

		YES	NO
B1.	Male or female; Age 50 years or older:	☐1	☐0
B2.	Heart failure as defined in Table 1. One symptom must be present at the time of screening and one sign must be present in the last 12 months:	☐1	☐0

TABLE 1. Criteria for Diagnosing Heart Failure

SYMPTOMS (at least one must be present at the time of screening)	SIGNS (at least one in last 12 mo.)
• Paroxysmal nocturnal dyspnea	• Any rales post cough
• Orthopnea	• Jugular venous pressure (JVP) ≥ 10 cm H_2O
• Dyspnea on mild or moderate exertion	• Lower extremity edema
	• Chest x-ray demonstrating pleural effusion, pulmonary congestion, or cardiomegaly

B3.	Left ventricular ejection fraction (ideally obtained by echocardiography, although radionuclide ventriculography and angiography are acceptable) ≥ 45% (per local reading). The ejection fraction must have been obtained within 6 months prior to randomization and after any MI or other event that would affect ejection fraction:	☐1	☐0
B4.	Controlled systolic BP, defined as a target systolic BP < 140 mm Hg. Subjects with BP up to and including 160 mm Hg are eligible for enrollment if on 3 or more medications to control BP:	☐1	☐0
B5.	Serum potassium < 5.0 mmol/L prior to randomization:	☐1	☐0
B6a.	At least one hospital admission in the last 12 months for which heart failure was a major component of the hospitalization. Transient heart failure in the context of myocardial infarction (MI) does not qualify:	☐1	☐0
	OR		
B6b.	Brain natriuretic peptide (BNP) in the last 30 days ≥ 100 pg/ml or N-terminal pro-BNP ≥ 360 pg/ml and not explained by another disease entity:	☐1	☐0

SECTION B: INCLUSION CRITERIA (continued)

		YES	NO	N/A
B7.	Women of child-bearing potential must have a negative serum/urine pregnancy test within 72 hours prior to randomization, must not be lactating, and must agree to use an effective method of contraception during the entire course of study participation:	☐1	☐0	☐-1
B8.	Willing to comply with scheduled monitoring visits, as outlined in Table 2 of the protocol:	☐1	☐0	
B9.	Informed consent form signed by the subject:	☐1	☐0	

SECTION C: EXCLUSION CRITERIA

		YES	NO
C1.	Severe systemic illness with life expectancy judged less than three years:	☐1	☐0
C2.	Chronic pulmonary disease requiring home O_2, oral steroid therapy or hospitalization for exacerbation within 12 months, or significant chronic pulmonary disease in the opinion of the investigator:	☐1	☐0
C3.	Known infiltrative or hypertrophic obstructive cardiomyopathy or known pericardial constriction:	☐1	☐0
C4.	Primary hemodynamically significant uncorrected valvular heart disease, obstructive or regurgitant, or any valvular disease expected to lead to surgery during the trial:	☐1	☐0
C5.	Atrial fibrillation with a resting heart rate > 90 bpm:	☐1	☐0
C6.	Myocardial infarction in past 90 days:	☐1	☐0
C7.	Coronary artery bypass graft surgery in past 90 days:	☐1	☐0
C8.	Percutaneous coronary intervention in past 30 days:	☐1	☐0
C9.	Heart transplant recipient:	☐1	☐0
C10.	Currently implanted left ventricular assist device:	☐1	☐0
C11.	Stroke in past 90 days:	☐1	☐0

SECTION C: EXCLUSION CRITERIA (continued)

		YES	NO
C12.	Systolic blood pressure (SBP) > 160 mm Hg:	☐1	☐0
C13.	Known orthostatic hypotension:	☐1	☐0
C14.	Gastrointestinal disorder that could interfere with study drug absorption:	☐1	☐0
C15.	Use of any aldosterone antagonist or potassium sparing medication in last 14 days:	☐1	☐0
C16.	Known intolerance to aldosterone antagonists:	☐1	☐0
C17.	Current lithium use:	☐1	☐0
C18.	Current participation (including prior 30 days) in any other therapeutic trial:	☐1	☐0
C19.	Any condition that, in the opinion of the investigator, may prevent the subject from adhering to the trial protocol:	☐1	☐0
C20.	History of hyperkalemia (serum potassium ≥ 5.5 mmol/L) in the past six months or serum potassium ≥ 5.0 mmol/L within the past two weeks:	☐1	☐0
C21.	Severe renal dysfunction, defined as an estimated glomerular filtration rate (GFR) < 30 ml/min (per the Modification of Diet in Renal Disease (MDRD) 4-component study equation). Subjects with serum creatinine ≥ 2.5 mg/dl are also excluded even if their GFR is ≥ 30 ml/min:	☐1	☐0
C22.	Known chronic hepatic disease, defined as aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels > 3.0 times the upper limit of normal as read at the local lab:	☐1	☐0

SECTION D: ELIGIBILITY STATUS

D1. Are all inclusion criteria questions answered YES? ☐1 YES ☐0 NO

D2. Are all exclusion criteria questions answered NO? ☐1 YES ☐0 NO

D3. Date eligibility determined: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

D4. Subject status on this date: ☐1 INPATIENT ☐2 OUTPATIENT

SECTION D: ELIGIBILITY STATUS (continued)

D5. Has the subject used any aldosterone antagonist or potassium sparing medication in 30 days prior to the date that eligibility was determined? ☐1 YES ☐0 NO

	a. Aldosterone Antagonist / Potassium Sparing Medication	b. Date last used (DD-MMM-YYYY)
1.		__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y
2.		__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y
3.		__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y
4.		__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y
5.		__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y

SECTION E: BNP STATUS

E1. Has the subject had brain natriuretic peptide (BNP) or N-terminal pro-BNP in the 30 days prior to the date that eligibility was determined? ☐1 YES ☐0 NO

E2. BNP ☐1 Brain natriuretic peptide (BNP)
☐2 N-terminal pro-BNP

a. Result in pg/ml: __ __ __ __

Treatment Of Preserved Cardiac function heart failure with an Aldosterone anTagonist

T002 Eligibility
T002 Version D

SECTION A: GENERAL INFORMATION

A1. Subject ID:

A2. Subject initials:

A3. Visit:

SECTION B: INCLUSION CRITERIA

B1. Male or female age 50 years or older: ☐ Yes ☐ No

B2. Heart failure as defined in Table 1. One symptom must be present at the time of screening and one sign must be present in the last 12 months: ☐ Yes ☐ No

TABLE 1. Criteria for Diagnosing Heart Failure	
SYMPTOMS (at least one must be present at the time of screening)	SIGNS (at least one in last 12 mo.)
• Paroxysmal nocturnal dyspnea	• Any rales post cough
• Orthopnea	• Jugular venous pressure (JVP) ≥ 10 cm H_2O
• Dyspnea on mild or moderate exertion	• Lower extremity edema
	• Chest x-ray demonstrating pleural effusion, pulmonary congestion, or cardiomegaly

B3. Left ventricular ejection fraction (ideally obtained by echocardiography, although radionuclide ventriculography and angiography are acceptable) ≥ 45% (per local reading). The ejection fraction must have been obtained within 6 months prior to randomization and after any MI or other event that would affect ejection fraction: ☐ Yes ☐ No

B4. Controlled systolic BP, defined as a target systolic BP < 140 mm Hg. Subjects with BP up to and including 160 mm Hg are eligible for enrollment if on 3 or more medications to control BP: ☐ Yes ☐ No

B5. Serum potassium < 5.0 mmol/L prior to randomization: ☐ Yes ☐ No

B6a. At least one hospital admission in the last 12 months for which heart failure was a major component of the hospitalization. Transient heart failure in the context of myocardial infarction (MI) does not qualify: ☐ Yes ☐ No

OR

B6b. Brain natriuretic peptide (BNP) in the last 60 days ≥ 100 pg/ml or N-terminal pro-BNP ≥ 360 pg/ml and not explained by another disease entity: ☐ Yes ☐ No

B7. Women of child-bearing potential must have a negative serum/urine pregnancy test within 72 hours prior to randomization, must not be lactating, and must agree to use an effective method of contraception during the ☐ Yes ☐ No ☐ N/A

	entire course of study participation:	
B8.	Willing to comply with scheduled monitoring visits, as outlined in Table 2 of the protocol:	Yes No
B9.	Informed consent form signed by the subject:	Yes No

SECTION C: EXCLUSION CRITERIA

C1.	Severe systemic illness with life expectancy judged less than three years:	Yes No
C2.	Chronic pulmonary disease requiring home O_2, oral steroid therapy or hospitalization for exacerbation within 12 months, or significant chronic pulmonary disease in the opinion of the investigator:	Yes No
C3.	Known infiltrative or hypertrophic obstructive cardiomyopathy or known pericardial constriction:	Yes No
C4.	Primary hemodynamically significant uncorrected valvular heart disease, obstructive or regurgitant, or any valvular disease expected to lead to surgery during the trial:	Yes No
C5.	Atrial fibrillation with a resting heart rate > 90 bpm:	Yes No
C6.	Myocardial infarction in past 90 days:	Yes No
C7.	Coronary artery bypass graft surgery in past 90 days:	Yes No
C8.	Percutaneous coronary intervention in past 30 days:	Yes No
C9.	Heart transplant recipient:	Yes No
C10.	Currently implanted left ventricular assist device:	Yes No
C11.	Stroke in past 90 days:	Yes No
C12.	Systolic blood pressure (SBP) > 160 mm Hg:	Yes No
C13.	Known orthostatic hypotension:	Yes No
C14.	Gastrointestinal disorder that could interfere with study drug absorption:	Yes No
C15.	Use of any aldosterone antagonist or potassium sparing medication in last 14 days:	Yes No
C16.	Known intolerance to aldosterone antagonists:	Yes No
C17.	Current lithium use:	Yes No
C18.	Current participation (including prior 30 days) in any other therapeutic trial:	Yes No
C19.	Any condition that, in the opinion of the investigator, may prevent the subject from adhering to the trial protocol:	Yes No
C20.	History of hyperkalemia (serum potassium $\geq$ 5.5 mmol/L) in the past six months or serum potassium $\geq$ 5.0 mmol/L within the past two weeks:	Yes No
C21.	Severe renal dysfunction, defined as an estimated glomerular filtration rate (GFR) < 30 ml/min (per the Modification of Diet in Renal Disease (MDRD) 4-component study equation). Subjects with serum creatinine $\geq$ 2.5 mg/dl are also excluded even if their	Yes No

GFR is ≥ 30 ml/min:

C22. Known chronic hepatic disease, defined as aspartate aminotransferase (AST) and alanine aminotransferase (ALT) levels > 3.0 times the upper limit of normal as read at the local lab: ☐ Yes ☐ No

SECTION D: ELIGIBILITY STATUS

D1. Are all inclusion criteria questions answered YES? ☐ Yes ☐ No

D2. Are all exclusion criteria questions answered NO? ☐ Yes ☐ No

D3. Date eligibility determined: DD-MMM-YYYY

D4. Subject status on this date: ☐ Inpatient ☐ Outpatient

D5. Has the subject used any aldosterone antagonist or potassium sparing medication in 30 days prior to the date that eligibility was determined? ☐ Yes ☐ No

	a. Aldosterone Antagonist / Potassium Sparing Medication	b. Date last used (DD-MMM-YYYY)
		DD-MMM-YYYY

SECTION B: INCLUSION CRITERIA

E1. Has the subject had brain natriuretic peptide (BNP) or N-terminal pro-BNP in the 60 days prior to the date that eligibility was determined? ☐ Yes ☐ No

E2. BNP: ☐ Brain natriuretic peptide (BNP) ☐ N-terminal pro-BNP

a. Result in pg/ml:

ELECTRONIC SIGNATURE

This form has not been signed.

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: BASELINE

SECTION B: SUBJECT INFORMATION

B1. Date of birth: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Gender: ☐1 MALE ☐2 FEMALE

B3. Race: (self-reported)
(please check all that apply)

- ☐ WHITE OR CAUCASIAN
- ☐ BLACK OR AFRICAN AMERICAN
- ☐ ASIAN
- ☐ AMERICAN INDIAN OR ALASKAN NATIVE
- ☐ NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER
- ☐ OTHER
  - i. If OTHER, specify: _____

B4. Is subject of Hispanic, Latino, or Spanish origin? (self-reported) ☐1 YES ☐0 NO

Clinical Evidence of Heart Failure

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: BASELINE

SECTION B: VISIT DATE

B1. Visit Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

SECTION C: HEART FAILURE SYMPTOM

	Heart failure symptom	a. Present at screening?	b. Experienced in past year?
C1.	Paroxysmal nocturnal dyspnea:	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN
C2.	Orthopnea:	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN
C3.	Dyspnea on mild or moderate exertion:	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN

SECTION D: HEART FAILURE SIGN

	Heart failure sign	a. Present at screening?	b. Experienced in past year?
D1.	Any rales post cough:	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN
D2.	Jugular venous pressure (JVP) ≥ 10 cm H_2O:	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN
D3.	Lower extremity edema:	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN
D4.	Chest x-ray demonstrating pleural effusion, pulmonary congestion, or cardiomegaly:	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN	☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN

SECTION E: MEASUREMENT OF THE LEFT VENTRICULAR EJECTION FRACTION

Please report the ejection fraction used to determine eligibility.

E1. Ejection fraction: ___ ___ %

E2. Assessment date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

E3. Source:

☐1 ECHOCARDIOGRAM

☐2 RADIONUCLIDE VENTRICULOGRAPHY

☐3 ANGIOGRAPHY

PLEASE NOTE: THE ECHOCARDIOGRAM UTILIZED TO DETERMINE ELIGIBILITY MUST BE SUBMITTED TO THE CTCC. (NOTE: VIDEO COPY OR DIGITAL IMAGE IS ACCEPTABLE)

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: BASELINE

SECTION B: MEDICAL HISTORY

B1. Visit Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

Has the subject experienced any of the following:

B2. Previous hospitalization for CHF: ☐1 YES ☐0 NO **(B3)**

If YES:

a. Specify the discharge date from the last hospitalization: __ __ - __ __ __ - __ __ __ __
D D / M M M / Y Y Y Y

B3. Previous myocardial infarction: ☐1 YES ☐0 NO **(B4)**

a. If YES: specify date of most recent MI. __ __ - __ __ __ - __ __ __ __
D D / M M M / Y Y Y Y

B4. Stroke: ☐1 YES ☐0 NO **(B5)**

a. If YES: specify date of most recent stroke. __ __ - __ __ __ - __ __ __ __
D D / M M M / Y Y Y Y

B5. Coronary artery bypass graft surgery: ☐1 YES ☐0 NO **(B6)**

a. If YES: specify date of most recent CABG: __ __ - __ __ __ - __ __ __ __
D D / M M M / Y Y Y Y

B6. Percutaneous coronary revascularization: ☐1 YES ☐0 NO **(B7)**

a. If YES: specify date of most recent PCR: __ __ - __ __ __ - __ __ __ __
D D / M M M / Y Y Y Y

SECTION B: MEDICAL HISTORY (continued)

		YES	NO	
B7.	Angina Pectoris:	☐1	☐0	
B8.	Chronic Obstructive Pulmonary Disease:	☐1	☐0	
B9.	Asthma:	☐1	☐0	
B10.	Hypertension:	☐1	☐0	
B11.	Peripheral Arterial Disease:	☐1	☐0	
B12.	Dyslipidemia:	☐1	☐0	
B13.	Implanted cardioverter defibrillator:	☐1	☐0	
B14.	Pacemaker implanted:	☐1	☐0	
B15.	Atrial fibrillation:	☐1	☐0	**(B16)**
	a. If YES: Paroxysmal atrial fibrillation:	☐1	☐0	
	b. If YES: Chronic atrial fibrillation:	☐1	☐0	
B16.	Thyroid disease:	☐1	☐0	**(B17)**
	a. If YES: Hyperthyroidism:	☐1	☐0	
	b. If YES: Hypothyroidism:	☐1	☐0	
B17.	Diabetes Mellitus:	☐1	☐0	**(B18)**

			UNITS	
a.	If YES, age of onset:	___ ___	☐1 MONTHS	☐2 YEARS
b.	Duration since diagnosis:	___ ___	☐1 MONTHS	☐2 YEARS

c. Treatment for diabetes mellitus: (check all that apply)

- ☐ INSULIN
- ☐ ORAL THERAPY
- ☐ DIET CONTROL
- ☐ OTHER
  - a. OTHER, specify: _____

Diabetes Mellitus **(continued)**

		YES	NO	
d.	Known microvascular complications:	☐1	☐0	**(B18)**
If YES,				
i.	Retinopathy:	☐1	☐0	
ii.	Nephropathy:	☐1	☐0	
iii.	Neuropathy:	☐1	☐0	

B18. Bone fracture after the age of 45: ☐1 ☐0 **(C1)**

a. If YES, specify the site:
- ☐1 HIP **(C1)**
- ☐2 SPINE **(C1)**
- ☐3 WRIST **(C1)**
- ☐99 OTHER

b. If OTHER, please specify the site: _____

SECTION C: SOCIAL HISTORY

C1. Does the subject currently smoke: ☐1 YES ☐0 NO **(C2)**

a. If YES, average number of cigarettes a day: ___ ___

b. Number of years smoking: ___ ___ **(C3)**

C2. Has the subject ever been a smoker: ☐1 YES ☐0 NO **(C3)**

a. If YES, how many years since quitting? ___ ___

C3. How many alcoholic drinks has the subject consumed in the past week? (include beer, wine and hard liquor(e.g. vodka, rum, etc…)

☐1 0 ☐2 1 - 4 ☐3 5 - 10 ☐4 11 - 20 ☐5 > 20

What has the subject's usual pattern of exercise been during the past 2 weeks?

		a. # of times/week	b. # of minutes each time
C4.	Heavy (jogging, tennis, strenuous gardening, or housework, etc…)	___ ___	___ ___ ___
C5.	Medium (brisk walking, stationary bike, moderate gardening or housework, etc…)	___ ___	___ ___ ___
C6.	Light (slow walking, etc…)	___ ___	___ ___ ___

C7. Does the subject currently live alone? ☐1 YES **(C8a)** ☐0 NO

a. Does the subject live with a spouse or significant other? ☐1 YES ☐0 NO

What is the subject's usual pattern for nutrition?

C8. How much salt does the subject add during cooking to the following homemade foods per serving?

		NONE	1/8 tsp.	1/4 tsp.	1/2 + tsp.
a.	Staple food (e.g. rice, pasta, potatoes, etc)	☐0	☐1	☐2	☐3
b.	Soup	☐0	☐1	☐2	☐3
c.	Meat	☐0	☐1	☐2	☐3
d.	Vegetables	☐0	☐1	☐2	☐3

C9. How many shakes of salt does the subject add to their food at the table each day? ___ ___ shakes

C10. What percent of the subject's noon and evening meals are prepared at home (exclude commercially prepared meals)?

☐0 ALMOST NONE
☐1 25%
☐2 50%
☐3 75%
☐4 ALMOST ALL

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: BASELINE

SECTION B: PHYSICAL EXAM

B1. Exam Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

Physical findings to report:

	Body system	a. Normal?	b. If NO, briefly describe:
B2.	Pulmonary	☐$_1$ YES **(B3)** ☐$_0$ NO ☐$_{-8}$ UNKNOWN **(B3)**	_____
B3.	Cardiovascular	☐$_1$ YES **(B4)** ☐$_0$ NO ☐$_{-8}$ UNKNOWN **(B4)**	_____
B4.	Neurological	☐$_1$ YES **(B5)** ☐$_0$ NO ☐$_{-8}$ UNKNOWN **(B5)**	_____

B5. Local assessment of current functional status according to New York Heart Association (NYHA):

☐$_1$ **CLASS I -** No limitation: Ordinary physical activity does not cause undue fatigue, dyspnea, or palpitation.

☐$_2$ **CLASS II -** Slight limitation of physical activity: Such patients are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or angina.

☐$_3$ **CLASS III -** Marked limitation of physical activity: Although patients are comfortable at rest, less than ordinary activity will lead to symptoms.

☐$_4$ **CLASS IV -** Inability to carry on any physical activity without discomfort: Symptoms of congestive failure are present even at rest.

SECTION B: PHYSICAL EXAM (continued)

		a. Units		b. Value
B6.	Height:	☐1 cm	☐2 inches	___ ___ ___
B7.	Weight:	☐1 kg	☐2 lb	___ ___ ___
B8.	Waist Circumference:	☐1 cm	☐2 inches	___ ___ ___
B9.	Heart rate:			___ ___ ___ beats/min

		a. Value	b. Method	
B10.	Systolic blood pressure:	___ ___ ___ mm Hg	☐1 MANUAL	☐2 AUTOMATED
B11.	Diastolic blood pressure:	___ ___ ___ mm Hg		

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: ☐ Baseline ☐ 4 week ☐ 8 week ☐ 4 month ☐ 8 month
☐ 12 month ☐ 18 month ☐ 24 month ☐ 30 month ☐ 36 month
☐ 42 month ☐ 48 month ☐ 54 month

SECTION B: CURRENT MEDICATIONS

B1. Visit Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Were there any changes to the subject's medications (other than study drug) since the last visit: ☐1 YES ☐0 NO **(END)**

B3. Is the subject currently taking a diuretic: ☐1 YES ☐0 NO **(B4)**

	a. MEDICATION	b. TOTAL DAILY DOSE	c. UNITS	
1.				**Units Codes:** Mg=1 G=2 Ml=3 Puff=4 Other=99
2.				
3.				

B4. Is the subject currently taking an ACE inhibitor: ☐1 YES ☐0 NO **(B5)**

	a. MEDICATION	b. TOTAL DAILY DOSE	c. UNITS	
1.				**Units Codes:** Mg=1 G=2 Ml=3 Puff=4 Other=99
2.				

SECTION B: CURRENT MEDICATIONS (continued)

B5. Is the subject currently taking an Angiotensin II Receptor Blocker (ARB): ☐1 YES ☐0 NO **(B6)**

	a. MEDICATION	b. TOTAL DAILY DOSE	c. UNITS	
1.				**Units Codes:** Mg=1 G=2 Ml=3 Puff=4 Other=99
2.				

B6. Is the subject currently taking a ß-blocker: ☐1 YES ☐0 NO **(B7)**

	a. MEDICATION	b. TOTAL DAILY DOSE	c. UNITS	
1.				**Units Codes:** Mg=1 G=2 Ml=3 Puff=4 Other=99
2.				
3.				

B7. Is the subject currently taking a calcium channel blocker: ☐1 YES ☐0 NO **(B8)**

	a. MEDICATION	b. TOTAL DAILY DOSE	c. UNITS	
1.				**Units Codes:** Mg=1 G=2 Ml=3 Puff=4 Other=99
2.				
3.				

B8. Is the subject currently taking a hypoglycemic agent: ☐1 YES ☐0 NO **(B9)**

	a. MEDICATION	b. TOTAL DAILY DOSE	c. UNITS	
1.				**Units Codes:** Mg=1 G=2 Ml=3 Puff=4 Other=99
2.				
3.				

SECTION B: CURRENT MEDICATIONS (continued)

B9. Is the subject currently taking any other cardiovascular medications (including antiplatelet and lipid lowering drugs): ☐1 YES ☐0 NO **(B10)**

	a. MEDICATION	b. TOTAL DAILY DOSE	c. UNITS	
1.				**Units Codes:** **Mg=1** **G=2** **Ml=3** **Puff=4** **Other=99**
2.				
3.				
4.				
5.				
6.				

B10. Is the subject currently taking any non-CV medications: ☐1 YES ☐0 NO **(END)**

	a. MEDICATION
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

Baseline Laboratory Tests

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: BASELINE

SECTION B: LABORATORY TESTS

B1. Was a blood specimen collected? ☐1 YES ☐0 NO **(END)**

B2. Collection date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

Electrolytes and Renal Function				
	Test	**a. Units**		**b. Result**
B3.	Sodium	☐1 mEq/L	☐2 mmol/L	___ ___ ___
B4.	Potassium	☐1 mEq/L	☐2 mmol/L	___ ___.___
B5.	Chloride	☐1 mEq/L	☐2 mmol/L	___ ___ ___
B6.	Bicarbonate/ Total CO_2	☐1 mEq/L	☐2 mmol/L	___ ___
B7.	BUN	☐1 mg/dl	☐2 mmol/L	___ ___ ___. ___
B8.	Creatinine	☐1 mg/dl	☐2 µmol/L	___ ___ ___. ___

B9. Blood Glucose ☐1 FASTING ☐2 RANDOM

a. Units ☐1 mg/dl ☐2 mmol/L **b. Result:** ___ ___ ___. ___

SECTION B: LABORATORY TESTS (continued)

Complete Blood Count (CBC)				
	Test	**a. Units**		**b. Result**
B10.	WBC count	☐1 k/uL or x10^3/µl	☐2 x10^9/L	__ __.__
B11.	Hematocrit	☐1 %	☐2 1	__ __ __. __ __
B12.	Hemoglobin	☐1 g/dl	☐2 g/L	__ __ __.__
B13.	Platelet count	☐1 k/uL or x10^3/µl	☐2 x10^9/L	__ __ __

Liver Function Test (LFT)				
	Test	**a. Units**		**b. Result**
B14.	Alanine Aminotransferase (ALT)	☐1 U/L	☐2 µkat/L	__ __ __. __
B15.	Alkaline phosphatase (ALP)	☐1 U/L	☐2 µkat/L	__ __ __. __
B16.	Aspartate Aminotransferase (AST)	☐1 U/L	☐2 µkat/L	__ __ __. __
B17.	Total Bilirubin	☐1 mg/dl	☐2 µmol/L	__ __. __
B18.	Albumin	☐1 g/dl	☐2 g/L	__ __. __

Baseline Laboratory Tests

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: BASELINE

SECTION B: LABORATORY TESTS

B1. Was a blood specimen collected? ☐1 YES ☐0 NO **(END)**

B2. Collection date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

Electrolytes and Renal Function				
	Test	**a. Units**		**b. Result**
B3.	Sodium	☐1 mEq/L	☐2 mmol/L	___ ___ ___
B4.	Potassium	☐1 mEq/L	☐2 mmol/L	___ ___.___
B5.	Chloride	☐1 mEq/L	☐2 mmol/L	___ ___ ___
B6.	Bicarbonate/ Total CO_2	☐1 mEq/L	☐2 mmol/L	___ ___
B7.	BUN ☐-1 NA	☐1 mg/dl	☐2 mmol/L	___ ___ ___. ___
B8.	Creatinine	☐1 mg/dl	☐2 µmol/L	___ ___ ___. ___

B9. Blood Glucose ☐1 FASTING ☐2 RANDOM

a. Units ☐1 mg/dl ☐2 mmol/L **b. Result:** ___ ___ ___. ___

SECTION B: LABORATORY TESTS (continued)

Complete Blood Count (CBC)				
	Test	**a. Units**		**b. Result**
B10.	WBC count	☐1 k/uL or x10^3/µl	☐2 x10^9/L	__ __.__
B11.	Hematocrit	☐1 %	☐2 1	__ __ __. __ __
B12.	Hemoglobin	☐1 g/dl	☐2 g/L	__ __ __.__
B13.	Platelet count	☐1 k/uL or x10^3/µl	☐2 x10^9/L	__ __ __

Liver Function Test (LFT)				
	Test	**a. Units**		**b. Result**
B14.	Alanine Aminotransferase (ALT)	☐1 U/L	☐2 µkat/L	__ __ __. __
B15.	Alkaline phosphatase (ALP)	☐1 U/L	☐2 µkat/L	__ __ __. __
B16.	Aspartate Aminotransferase (AST)	☐1 U/L	☐2 µkat/L	__ __ __. __
B17.	Total Bilirubin	☐1 mg/dl	☐2 µmol/L	__ __. __
B18.	Albumin	☐1 g/dl	☐2 g/L	__ __. __

Urine Microalbuminuria

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: ☐ Baseline ☐ 12 month ☐ 24 month ☐ 36 month ☐ 48 month

SECTION B: URINE MICROALBUMINURIA

B1. Was a urine sample collected? ☐$_1$ YES ☐$_0$ NO **(END)**

B2. Collection date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

		a. Units	**b. Value**
B3.	Urine Microalbumin/Creatinine Ratio Result:	☐$_1$ mg/g ☐$_2$ mg/mmol	___ ___ ___ ___

B4. What is the urine dipstick measurement of proteinuria (if available)? ☐$_{-1}$ N/A ☐$_0$ 0 ☐$_1$ 1+ ☐$_2$ 2+ ☐$_3$ 3+

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: BASELINE

SECTION B: ELECTROCARDIOGRAM (ECG)

Please forward a copy of the ECG reported on this form to the CTCC.

B1. Date of ECG: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. QRS duration: __ __ __ msec

B3. Heart rate: __ __ __ beats/min

B4. Overall evaluation of ECG: ☐1 NORMAL **(END)** ☐2 ABNORMAL

If ABNORMAL, specify:

a) Atrial fibrillation/Flutter ☐1 YES ☐0 NO

b) Bundle branch block ☐0 NONE ☐1 RIGHT ☐2 LEFT ☐3 IVCD

c) Ventricular paced rhythm ☐1 YES ☐0 NO

d) Pathological Q waves ☐1 YES ☐0 NO

e) Left ventricular hypertrophy ☐1 YES ☐0 NO

f) Other ☐1 YES ☐0 NO **(END)**

i) If YES, specify: _____

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: BASELINE

SECTION B: PRE-RANDOMIZATION CRITERIA

B1. Date of Randomization: __ __ - __ __ __ - __ __ __ __ (D D - M M M - Y Y Y Y)

B2. Date of birth: __ __ - __ __ __ - __ __ __ __ (D D - M M M - Y Y Y Y)

B3. Gender: ☐1 MALE ☐2 FEMALE

B4. Is the subject Black or African American: (self-reported) ☐1 YES ☐0 NO

		a. Units	b. Result
B5.	Creatinine:	☐1 mg/dl ☐2 µmol/L	__ __ __. __

B6. Did the subject have at least one hospital admission in the last 12 months for which heart failure was a major component of the hospitalization: ☐1 YES ☐0 NO

B7. Did the subject have a brain natriuretic peptide (BNP) in the last 30 days ≥ 100 pg/ml or N-terminal pro-BNP ≥ 360 pg/ml and not explained by another disease entity: ☐1 YES ☐0 NO

B8. Did the subject meet ALL of the INCLUSION CRITERIA: ☐1 YES ☐0 NO

B9. Did the subject meet NONE of the EXCLUSION CRITERIA: ☐1 YES ☐0 NO

Please print out the randomization assignment, attach to this worksheet and place in subject's file.

Treatment Of Preserved Cardiac function heart failure with an Aldosterone anTagonist

T011 Randomization

SECTION A: GENERAL INFORMATION

A1. Subject ID:

A2. Subject Initials:

A3. Visit: BASELINE

SECTION B: PRE-RANDOMIZATION CRITERIA

B1.	Date of Randomization:	DD-MMM-YYYY	
B2.	Date of birth:	DD-MMM-YYYY	
B3.	Gender:	Male Female	
B4.	Is the subject Black or African American: (self-reported)	Yes No	
		a. Units	b. Result
B5.	Creatinine:	mg/dl µmol/L	GFR
B6.	Did the subject have at least one hospital admission in the last 12 months for which heart failure was a major component of the hospitalization:	Yes No	
B7.	Did the subject have a brain natriuretic peptide (BNP) in the last 60 days ≥ 100 pg/ml or N-terminal pro-BNP ≥ 360 pg/ml and not explained by another disease entity?	Yes No	
B8.	Did the subject meet ALL of the INCLUSION CRITERIA:	Yes No	
B9.	Did the subject meet NONE of the EXCLUSION CRITERIA:	Yes No	

ELECTRONIC SIGNATURE

This form has not been signed.

Study Drug Dispensing

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit:
☐ Baseline ☐ 4 week ☐ 8 week ☐ 4 month ☐ 8 month
☐ 12 month ☐ 18 month ☐ 24 month ☐ 30 month ☐ 36 month
☐ 42 month ☐ 48 month ☐ 54 month

SECTION B: STUDY DRUG DISTRIBUTION

B1. Visit Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Initials of person who dispensed study drug: ____ ____ ____

B3. Number of bottle(s) dispensed: ____

			Treatment Allocation Code	Lot number
B4.	Bottle label(s):	a.	____	____ ____ ____ ____ ____
		b.	____	____ ____ ____ ____ ____
		c.	____	____ ____ ____ ____ ____
		d.	____	____ ____ ____ ____ ____
		e.	____	____ ____ ____ ____ ____
		f.	____	____ ____ ____ ____ ____
		g.	____	____ ____ ____ ____ ____
		h.	____	____ ____ ____ ____ ____
		i.	____	____ ____ ____ ____ ____
		j.	____	____ ____ ____ ____ ____

Follow-up Physical Exam

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit:
☐ 4 week ☐ 8 week ☐ 4 month ☐ 8 month ☐ 12 month
☐ 18 month ☐ 24 month ☐ 30 month ☐ 36 month ☐ 42 month
☐ 48 month ☐ 54 month

SECTION B: PHYSICAL EXAM

B1. Visit Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B1a. Was a physical exam done: ☐$_1$ YES ☐$_0$ NO **(B5)**

Physical findings to report:

	Body system	a. Normal?	b. If NO, briefly describe:
B2.	Pulmonary	☐$_1$ YES **(B3)** ☐$_0$ NO ☐$_{-8}$ UNKNOWN **(B3)**	_____
B3.	Cardiovascular	☐$_1$ YES **(B4)** ☐$_0$ NO ☐$_{-8}$ UNKNOWN **(B4)**	_____
B4.	Neurological	☐$_1$ YES **(B5)** ☐$_0$ NO ☐$_{-8}$ UNKNOWN **(B5)**	_____

B5. Local assessment of current functional status according to New York Heart Association (NYHA):

☐$_1$ **CLASS I -** No limitation: Ordinary physical activity does not cause undue fatigue, dyspnea, or palpitation.

☐$_2$ **CLASS II -** Slight limitation of physical activity: Such patients are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea, or angina.

☐$_3$ **CLASS III -** Marked limitation of physical activity: Although patients are comfortable at rest, less than ordinary activity will lead to symptoms.

☐$_4$ **CLASS IV -** Inability to carry on any physical activity without discomfort: Symptoms of congestive failure are present even at rest.

SECTION B: PHYSICAL EXAM (continued)

		a. Units		b. Value
B6.	Weight:	☐1 kg	☐2 lb	___ ___ ___
B7.	Waist Circumference:	☐1 cm	☐2 inches	___ ___ ___
B8.	Heart rate:			___ ___ ___ beats/min

		a. Value	b. Method	
B9.	Systolic blood pressure:	___ ___ ___ mm Hg	☐1 MANUAL	☐2 AUTOMATED
B10.	Diastolic blood pressure:	___ ___ ___ mm Hg		

SECTION C: HEART FAILURE SYMPTOM

	Heart failure symptom	Currently experiencing?		
C1.	Paroxysmal nocturnal dyspnea:	☐1 YES	☐0 NO	☐-8 UNKNOWN
C2.	Orthopnea:	☐1 YES	☐0 NO	☐-8 UNKNOWN
C3.	Dyspnea on mild or moderate exertion:	☐1 YES	☐0 NO	☐-8 UNKNOWN

SECTION D: HEART FAILURE SIGN

	Heart failure sign	Currently experiencing?		
D1.	Any rales post cough:	☐1 YES	☐0 NO	☐-8 UNKNOWN
D2.	Jugular venous pressure (JVP) ≥ 10 cm H_2O:	☐1 YES	☐0 NO	☐-8 UNKNOWN
D3.	Lower extremity edema:	☐1 YES	☐0 NO	☐-8 UNKNOWN
D4.	Chest x-ray demonstrating pleural effusion, pulmonary congestion, or cardiomegaly:	☐1 YES	☐0 NO	☐-8 UNKNOWN

Event Questionnaire

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit:
☐ 4 week ☐ 8 week ☐ 4 month ☐ 8 month ☐ 12 month
☐ 18 month ☐ 24 month ☐ 30 month ☐ 36 month ☐ 42 month
☐ 48 month ☐ 54 month

SECTION B: EVENTS

B1.	Visit Date: __ __ - __ __ __ - __ __ __ __ (D D - M M M - Y Y Y Y)		
B2.	Have there been any hospitalizations for the management of heart failure since the last visit?	☐$_1$ YES	☐$_0$ NO
B3.	Has there been any newly diagnosed illness since the last visit?	☐$_1$ YES	☐$_0$ NO **(B12)**
B4.	New onset of diabetes mellitus:	☐$_1$ YES	☐$_0$ NO
B5.	New onset of atrial fibrillation:	☐$_1$ YES	☐$_0$ NO
B6.	New onset MI (fatal & non-fatal):	☐$_1$ YES	☐$_0$ NO
B7.	New onset of stroke (fatal & non-fatal):	☐$_1$ YES	☐$_0$ NO
B8.	Deterioration of renal function:	☐$_1$ YES	☐$_0$ NO
B9.	Aborted cardiac arrest:	☐$_1$ YES	☐$_0$ NO
B10.	New or worsening symptoms of CHF:	☐$_1$ YES	☐$_0$ NO

SECTION B: EVENTS (continued)

B11. Other: ☐1 YES ☐0 NO **(B12)**

a. If OTHER, please specify: _____

If YES to B2, B4 through B10, please complete the corresponding event form.

B12. Have there been any therapeutic interventions since the last visit? ☐1 YES ☐0 NO **(END)**

a. Medication intervention: ☐1 YES ☐0 NO

If YES, please note changes on medications form.

b. Surgical intervention: ☐1 YES ☐0 NO **(END)**

i. If YES, procedure: _____

If YES and meets the definition of an AE, please complete an AE form.

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit:
☐ 4 week ☐ 8 week ☐ 4 month ☐ 8 month ☐ 12 month
☐ 18 month ☐ 24 month ☐ 30 month ☐ 36 month ☐ 42 month
☐ 48 month ☐ 54 month

SECTION B: EVENTS

B1. Visit Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Have there been any hospitalizations for the management of heart failure since the last visit? ☐$_1$ YES ☐$_0$ NO

a. Number of hospitalizations for the management of heart failure since the last visit __ __

B3. Has there been any newly diagnosed illness since the last visit? ☐$_1$ YES ☐$_0$ NO

B4. New onset of diabetes mellitus: ☐$_1$ YES ☐$_0$ NO

B5. New onset of atrial fibrillation: ☐$_1$ YES ☐$_0$ NO

a. Number of events with new onset of atrial fibrillation since the last visit __ __

B6. Cardiac marker elevation or myocardial infarction (fatal & non-fatal): ☐$_1$ YES ☐$_0$ NO

a. Number of events with cardiac marker elevation or myocardial infarction since the last visit __ __

B7. Stroke (fatal & non-fatal): ☐$_1$ YES ☐$_0$ NO

a. Number of events with stroke since the last visit __ __

SECTION B: EVENTS (continued)

B8. Deterioration of renal function: ☐1 YES ☐0 NO

a. Number of events with deterioration of renal function since the last visit __ __

B9. Aborted cardiac arrest or hospitalization for the management of ventricular tachycardia: ☐1 YES ☐0 NO

a. Number of events with aborted cardiac arrest or hospitalization for the management of ventricular tachycardia since the last visit __ __

B10. New or worsening symptoms of CHF: ☐1 YES ☐0 NO

a. Was there any hospitalization during the time frame of the new or worsening symptoms of CHF? ☐1 YES ☐0 NO

b. Number of hospitalizations during the time frame of new or worsening symptoms of CHF since the last visit __ __

B11. Other: ☐1 YES ☐0 NO **(B12)**

a. If OTHER, please specify: _____

If YES to B2, B4 through B10, please complete the corresponding event form.

B12. Have there been any therapeutic interventions since the last visit? ☐1 YES ☐0 NO **(END)**

a. Medication intervention: ☐1 YES ☐0 NO

If YES, please note changes on medications form.

b. Surgical intervention: ☐1 YES ☐0 NO **(END)**

i. If YES, procedure: _____

If YES and meets the definition of an AE, please complete an AE form.

Study Drug Information

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit:
☐ Baseline ☐ 4 week ☐ 8 week ☐ 4 month ☐ 8 month
☐ 12 month ☐ 18 month ☐ 24 month ☐ 30 month ☐ 36 month
☐ 42 month ☐ 48 month ☐ 54 month

SECTION B: STUDY DRUG INFORMATION

B1. Visit Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Since the last visit, was the study drug dose **adjusted**?
☐1 YES ☐0 NO **(E1)**

B3. How was the study drug dose **adjusted**?
☐1 INCREASED **(C1)**
☐2 DECREASED **(C2)**
☐3 PERMANENT DISCONTINUATION **(D1)**
☐4 TEMPORARY DISCONTINUATION **(D3)**

SECTION C: DOSE ADJUSTMENT

C1. What was the date of **increase**: __ __ - __ __ __ - __ __ __ __ **(C4)**
D D - M M M - Y Y Y Y

C2. What was the date of **decrease**: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

C3. Reason for **decrease**:

	YES	NO
a. Hyperkalemia	☐1	☐0
b. Abnormal renal function	☐1	☐0
c. Gynecomastia	☐1	☐0
d. Subject's request	☐1	☐0
e. Other	☐1	☐0

1. If OTHER, please specify: _____

C4. What was the adjusted dose: **(E1)** ☐1 15 mg ☐2 30 mg ☐3 45 mg

SECTION D: DRUG DISCONTINUATION

D1. What was the date of **permanent discontinuation**: __ __/ __ __ __/ __ __ __ __
D D / M M M / Y Y Y Y

D2. Reason for **permanent discontinuation**:

	YES	NO
a. Persistent hyperkalemia (potassium ≥ 6.0 mmol/L)	☐1	☐0
b. Potassium ≥ 5.5 mmol/L and subject was on lowest dose of study drug	☐1	☐0
c. Abnormal renal function	☐1	☐0
d. Anaphylactoid reaction or intolerance	☐1	☐0
e. Breast tenderness or enlargement	☐1	☐0
f. Open label use of any aldosterone antagonist or potassium-sparing diuretic	☐1	☐0
g. Other	☐1	☐0

1. If Other, specify: _____ **(E1)**

D3. What was the date of **temporary discontinuation**: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

D4. Was study drug **re-initiated** prior to this visit: ☐1 YES ☐0 NO **(E1)**

a. If YES, enter date of **re-initiation**: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

D5. At what dose was study drug **re-initiated**: ☐1 15 mg ☐2 30 mg ☐3 45 mg

SECTION E: DRUG ACCOUNTABILITY

E1. Did the subject bring in study drug bottles to this visit? ☐1 YES ☐0 NO **(E6)**

E2. How many unopened bottles does the subject have: ____ ____

E3. How many empty bottles does the subject have: ____ ____

E4. How many opened bottles does the subject have: ____ ____ **(If zero, go to E6)**

E5. Please indicate the volume of residual tablets per bottle:

a. Bottle 1: ___ ___ ___ mL
b. Bottle 2: ___ ___ ___ mL
c. Bottle 3: ___ ___ ___ mL
d. Bottle 4: ___ ___ ___ mL
e. Bottle 5: ___ ___ ___ mL

E6. Newly prescribed dose: ☐0 0 mg ☐1 15 mg ☐2 30 mg ☐3 45 mg

E7. Additional drug dispensed at this visit? ☐1 YES ☐0 NO

If YES, please fill out the Study Drug Dispensing form.

Study Drug Information

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit:
☐ Baseline ☐ 4 week ☐ 8 week ☐ 4 month ☐ 8 month
☐ 12 month ☐ 18 month ☐ 24 month ☐ 30 month ☐ 36 month
☐ 42 month ☐ 48 month ☐ 54 month

SECTION B: STUDY DRUG INFORMATION

B1. Visit Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Was the study drug dose **increased, decreased, or temporarily discontinued** after the last visit and prior to the current visit?
☐1 YES ☐0 NO **(E1)**

B3. How was the study drug dose **adjusted**?
☐1 INCREASED **(C1)**
☐2 DECREASED **(C2)**
☐4 TEMPORARY DISCONTINUATION **(D3)**

SECTION C: DOSE ADJUSTMENT

C1. What was the date of **increase**: __ __ - __ __ __ - __ __ __ __ **(C4)**
D D - M M M - Y Y Y Y

C2. What was the date of **decrease**: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

C3. Reason for **decrease**:

	YES	NO
a. Hyperkalemia	☐1	☐0
b. Abnormal renal function	☐1	☐0
c. Gynecomastia	☐1	☐0
d. Subject's request	☐1	☐0
e. Other	☐1	☐0

1. If OTHER, please specify: _____

C4. What was the adjusted dose: **(E1)** ☐1 15 mg ☐2 30 mg ☐3 45 mg

SECTION D: TEMPORARY DISCONTINUATION

D1. What was the date of **temporary discontinuation**: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

D2. Was study drug **re-initiated** prior to this visit: ☐1 YES ☐0 NO **(E1)**

a. If YES, enter date of **re-initiation**: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

D3. At what dose was study drug **re-initiated**: ☐1 15 mg ☐2 30 mg ☐3 45 mg

SECTION E: DRUG ACCOUNTABILITY

E1. Did the subject bring in study drug bottles to this visit? ☐1 YES ☐0 NO **(E6)**

- **Please check the expiration date of all study drug bottles brought in.**
- **Any bottles which will expire before others should be used first.**
- **Any bottles which will expire before use should be returned to the site.**

E2. How many unopened bottles does the subject have? ____ ____

a. How many unopened bottles were returned to site (due to expiration or damage)? ____ ____

b. How many unopened bottles were reported as lost or thrown away by subject since the last visit? ____ ____

E3. How many empty bottles does the subject have? ____ ____

a. How many empty bottles were reported as lost or thrown away by subject since the last visit? ____ ____

E4. How many opened bottles does the subject have? ____ ____ **(If zero, go to E6)**

SECTION E: DRUG ACCOUNTABILITY (continued)

If tablets were measured, please provide volume. If tablets were counted, please provide number.

E5. Please indicate the volume or number of residual tablets measured per opened bottle, and please indicate if bottle was returned to the site (due to expiration date or damage):

a.	Bottle 1:	☐1 mL	☐2 tablets	___ ___ ___	Returned to site: ☐1
b.	Bottle 2:	☐1 mL	☐2 tablets	___ ___ ___	Returned to site: ☐1
c.	Bottle 3:	☐1 mL	☐2 tablets	___ ___ ___	Returned to site: ☐1
d.	Bottle 4:	☐1 mL	☐2 tablets	___ ___ ___	Returned to site: ☐1
e.	Bottle 5:	☐1 mL	☐2 tablets	___ ___ ___	Returned to site: ☐1

E6. Newly prescribed dose:

☐0 0 mg **(E7)**
☐1 15 mg **(E10)**
☐2 30 mg **(E10)**
☐3 45 mg **(E10)**

E7. Was study drug permanently discontinued? ☐1 YES **(E8)** ☐0 NO **(E10)**

E8. What was the date of **permanent discontinuation**: __ __/ __ __ __/ __ __ __ __
D D / M M M / Y Y Y Y

E9. Reason for **permanent discontinuation**:

	YES	NO
a. Persistent hyperkalemia (potassium ≥ 6.0 mmol/L)	☐1	☐0
b. Potassium ≥ 5.5 mmol/L and subject was on lowest dose of study drug	☐1	☐0
c. Abnormal renal function	☐1	☐0
d. Anaphylactoid reaction or intolerance	☐1	☐0
e. Breast tenderness or enlargement	☐1	☐0
f. Open label use of any aldosterone antagonist or potassium-sparing diuretic	☐1	☐0
g. Other	☐1	☐0

1. If Other, specify: _____ **(E1)**

E10. Additional drug dispensed at this visit? ☐1 YES ☐0 NO

If YES, please fill out the Study Drug Dispensing form.

Treatment Of Preserved Cardiac function heart failure with an Aldosterone anTagonist

T015 Study Drug Information
Ver. C

SECTION A: GENERAL INFORMATION

A1. Subject ID:

A2. Subject Initials:

A3. Visit:

SECTION B: STUDY DRUG INFORMATION

B1. Visit Date:

DD-MMM-YYYY

B2. Was the study drug dose increased, decreased, or temporarily discontinued after the last visit and prior to the current visit?

Yes No

B3. How was the study drug dose adjusted?

INCREASED
DECREASED
TEMPORARY DISCONTINUATION

SECTION C: DOSE ADJUSTMENT

C1. What was the date of increase:

DD-MMM-YYYY

C2. What was the date of decrease:

DD-MMM-YYYY

C3. Reason for decrease:

	YES	NO
a. Hyperkalemia		
b. Abnormal renal function		
c. Gynecomastia		
d. Subject's request		
e. Other		

1. If OTHER, please specify:

C4. What was the adjusted dose:

15 mg 30 mg 45 mg

SECTION D: TEMPORARY DISCONTINUATION

D1. What was the date of temporary discontinuation: DD-MMM-YYYY

D2. Was study drug re-initiated prior to this visit? YES NO

a. If YES, enter date of re-initiation: DD-MMM-YYYY

D3. At what dose was study drug re-initiated: 15 mg 30 mg 45 mg

SECTION E: DRUG ACCOUNTABILITY

E1. Did subject bring in study drug bottles to this visit? YES NO

E2. How many unopened bottles did the subject bring to this visit?

a. How many unopened bottles were returned to site (due to expiration or damage) at this visit?

Please indicate the allocation code and lot number for each unopened bottle that was returned to the site:

	Bottle #	Treatment Allocation Code	Lot #
a.	1		
b.	2		
c.	3		
d.	4		
e.	5		

E3. How many opened bottles (including empty bottles) did the subject bring to this visit?

If tablets were measured, please provide volume. If tablets were counted, please provide number.

Please specify the volume or number of residual tables measured per opened bottle and indicate if the bottle was returned to the site (due to expiration date or damage). If the bottle was returned to the site, enter its allocation code and lot number.

	Bottle #	Units	Number	Returned to site	Treatment Allocation Code	Lot #
a.	1	mL tablets		Yes No		
b.	2	mL tablets		Yes No		

c.	3	mL tablets		Yes No		
d.	4	mL tablets		Yes No		
e.	5	mL tablets		Yes No		

E4. How many unopened bottles were reported as lost or thrown away by subject since the last visit?

E5. How many opened (including empty) bottles were reported as lost or thrown away by the subject since the last visit?

E6. Newly prescribed dose: 0 mg 15 mg 30 mg 45 mg

E7. Was study drug permanently discontinued? Yes No

E8. What was the date of permanent discontinuation?
DD-MMM-YYYY

E9. Reason for permanent discontinuation:	YES	NO
a. Persistent hyperkalemia (potassium ≥ 6.0 mmol/L)		
b. Potassium ≥ 5.5 mmol/L and subject was on lowest dose of study drug		
c. Abnormal renal function		
d. Anaphylactoid reaction or intolerance		
e. Breast tenderness or enlargement		
f. Open label use of any aldosterone antagonist or potassium-sparing diuretic		
g. Other		

1. if Other, Specify:

E10. Additional drug dispensed at this visit? YES NO

If Yes, please fill out the Study Drug Dispensing form.

ELECTRONIC SIGNATURE

This form has not been signed.

Follow-up Laboratory Tests

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: ☐ Baseline ☐ 4 week ☐ 8 week ☐ 4 month ☐ 8 month
☐ 12 month ☐ 18 month ☐ 24 month ☐ 30 month ☐ 36 month
☐ 42 month ☐ 48 month ☐ 54 month

SECTION B: FOLLOW-UP LABORATORY TESTS

B1. Was a blood specimen collected? ☐1 YES ☐0 NO **(END)**

B2. Collection date: __ __/__ __ __/__ __ __ __
D D/ M M M/ Y Y Y Y

B3. Is this a follow-up blood draw based on a dose change? ☐1 YES ☐0 NO

	Test	a. Units		b. Result
B4.	Sodium	☐1 mEq/L	☐2 mmol/L	___
B5.	Potassium	☐1 mEq/L	☐2 mmol/L	___.__
B6.	Chloride	☐1 mEq/L	☐2 mmol/L	___
B7.	Bicarbonate/ Total CO_2	☐1 mEq/L	☐2 mmol/L	___
B8.	BUN	☐1 mg/dl	☐2 mmol/L	___.__
B9.	Creatinine	☐1 mg/dl	☐2 µmol/L	___.__

SECTION C: STUDY DRUG ASSESSMENT

C1. Was there a change in study drug dose based on the above blood specimen results? ☐1 YES ☐0 NO

Follow-up Laboratory Tests

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: ☐ Baseline ☐ 4 week ☐ 8 week ☐ 4 month ☐ 8 month
☐ 12 month ☐ 18 month ☐ 24 month ☐ 30 month ☐ 36 month
☐ 42 month ☐ 48 month ☐ 54 month

SECTION B: FOLLOW-UP LABORATORY TESTS

B1. Was a blood specimen collected? ☐1 YES ☐0 NO **(END)**

B2. Collection date: __ __/__ __ __/__ __ __ __
D D/ M M M/ Y Y Y Y

B3. Is this a follow-up blood draw based on a dose change? ☐1 YES ☐0 NO

	Test	a. Units		b. Result
B4.	Sodium	☐1 mEq/L	☐2 mmol/L	__ __ __
B5.	Potassium	☐1 mEq/L	☐2 mmol/L	__ __.__
B6.	Chloride	☐1 mEq/L	☐2 mmol/L	__ __ __
B7.	Bicarbonate/ Total CO_2	☐1 mEq/L	☐2 mmol/L	__ __
B8.	BUN ☐-1 NA	☐1 mg/dl	☐2 mmol/L	__ __ __. __
B9.	Creatinine	☐1 mg/dl	☐2 µmol/L	__ __ __. __

SECTION C: STUDY DRUG ASSESSMENT

C1. Was there a change in study drug dose based on the above blood specimen results? ☐1 YES ☐0 NO

Subject Participation

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit:
☐ Baseline ☐ 4 week ☐ 8 week ☐ 4 month ☐ 8 month
☐ 12 month ☐ 18 month ☐ 24 month ☐ 30 month ☐ 36 month
☐ 42 month ☐ 48 month ☐ 54 month

SECTION B: SUBJECT PARTICIPATION

B1. Date subject participation changed: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Indicate change in subject participation:

☐1 SUBJECT NO LONGER ON STUDY DRUG BUT COMING IN FOR STUDY VISITS

☐2 SUBJECT NO LONGER ON STUDY DRUG BUT WILL BE CONTACTED BY PHONE OR MAIL

☐3 SUBJECT NO LONGER ON STUDY DRUG BUT WILL BE MONITORED BY REVIEW OF MEDICAL RECORDS

☐4 SUBJECT WILL NOT ALLOW REVIEW OF MEDICAL RECORDS **(COMPLETE END OF STUDY FORM)**

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

SECTION B: CONGESTIVE HEART FAILURE (CHF)

B1. Event Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Location of the event:

- ☐ 1 HOSPITAL
- ☐ 2 EMERGENCY ROOM
- ☐ 3 OUTPATIENT
- ☐ 99 OTHER
  - a. If OTHER, specify:_____

B3a. Please indicate which type of symptoms the subject experienced: ☐ 1 NEW ☐ 2 WORSENING ☐ 3 BOTH

B3b. Check all new or worsening symptoms of CHF that the subject experienced with this event:

- ☐ INCREASING DYSPNEA ON EXERTION
- ☐ WORSENING ORTHOPNEA
- ☐ PAROXYSMAL NOCTURNAL DYSPNEA
- ☐ INCREASING FATIGUE/WORSENING EXERCISE TOLERANCE
- ☐ ALTERED MENTAL STATUS
- ☐ UNKNOWN
- ☐ OTHER
  - i. _____

B4. Check all new or worsening objective signs of CHF:

- ☐ RAPID WEIGHT GAIN
- ☐ PULMONARY EDEMA OR RALES
- ☐ ELEVATED JUGULAR VENOUS PRESSURE
- ☐ RADIOLOGIC SIGNS OF HEART FAILURE
- ☐ PERIPHERAL EDEMA
- ☐ ABDOMINAL DISTENSION WITH ASCITES
- ☐ S_3 GALLOP
- ☐ HEPATOJUGULAR REFLUX
- ☐ BRAIN NATRIURETIC PEPTIDE (BNP)
  - 1. Value: __ __ __ __ pg/mL
- ☐ N-terminal pro-BNP
  - 1. Value: __ __ __ __ __ pg/mL
- ☐ UNKNOWN
- ☐ OTHER
  - 1. If OTHER, specify:_____

SECTION B: CONGESTIVE HEART FAILURE (CHF) (continued)

B5. Did the subject require intravenous (IV) therapy to treat this event: ☐1 YES ☐0 NO **(B7a)**

B6. Which IV therapy was used: (check all that apply)

- ☐ VASODILATORS
- ☐ DIURETICS
- ☐ INOTROPES
- ☐ ULTRAFILTRATION
- ☐ INTRA-AORTIC BALLOON PUMP

B7. Did the subject require a change (i.e. initiation for new medication or dose change) of any of the following drug types to treat the new or worsening CHF:

		YES	NO
a.	Oral Diuretics	☐1	☐0
b.	ACE Inhibitors or Angiotensin Receptor Blockers (ARB's)	☐1	☐0
c.	ß-blocker's	☐1	☐0
d.	Spironolactone (non-study drug)	☐1	☐0
e.	Other	☐1	☐0

i. If OTHER, specify:_____

If YES, please indicate on medication form

SECTION C: REQUIRED DOCUMENTS

Below are the required documents. Please forward to NERI.

Discharge summary/Physician Narrative
Admission History and Physical/Admission Notes
Medication Logs

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

SECTION B: DETERIORATION OF RENAL FUNCTION

B1. Event Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Did the subject have progressive renal insufficiency defined as doubling of serum creatinine from baseline on two determinations separated by ≥ 28 days:

☐1 YES ☐0 NO

B3. Please provide relevant serum creatinine results documenting a twofold increase since baseline. The first collection date should occur on the Event date above. Please provide least one collection date which is 28 days or more after this first collection date.

	a. Last value to report?	b. Collection date	c. Units	d. Results	e. Upper Limit of Normal
1.	☐1	__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y	☐1 mg/dl ☐2 µmol/L	__ __ __. __	__ __ __. __
2.	☐1	__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y	☐1 mg/dl ☐2 µmol/L	__ __ __. __	__ __ __. __
3.	☐1	__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y	☐1 mg/dl ☐2 µmol/L	__ __ __. __	__ __ __. __
4.	☐1	__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y	☐1 mg/dl ☐2 µmol/L	__ __ __. __	__ __ __. __
5.	☐1	__ __ - __ __ __ - __ __ __ __ D D - M M M - Y Y Y Y	☐1 mg/dl ☐2 µmol/L	__ __ __. __	__ __ __. __

B4. Did the subject require renal replacement therapy:

☐1 DIALYSIS

☐2 TRANSPLANT

☐0 NEITHER

If subject required renal replacement therapy, please complete an AE form.

B5. Is there a reversible cause of renal failure:

☐1 YES ☐0 NO **(END)**

a. If YES, specify: _____

Treatment Of Preserved Cardiac function heart failure with an Aldosterone anTagonist

T021 Deterioration of Renal Function
Version: B

SECTION A: GENERAL INFORMATION

A1. Subject ID

A2. Subject initials

SECTION B: DETERIORATION OF RENAL FUNCTION

B1. Initial date of the elevated serum creatinine value:

DD-MMM-YYYY

B2. Did the subject have a doubling of serum creatinine from baseline to a value above the Upper Limit of Normal? ◯ Yes ◯ No

- If B2 is YES, then in B2a-B2c please provide an elevated serum creatinine value obtained from the event date in question B1, which is at least twice the baseline creatinine value (and above the Upper Limit of Normal).

- If B2 is NO, then proceed to question B4.

a. Units	b. Results	c. Upper Limit of Normal
◯ mg/dl ◯ µmol/L		

B3. Did the doubling of creatinine from baseline persist for ≥ 28 days? ◯ Yes ◯ No

- If B3 is YES, then in B3a please provide a second serum creatinine value obtained at least 28 days after the event date in question B1, which is at least twice the baseline creatinine value (and above the Upper Limit of Normal).

- If B3 is NO, then in B3a please provide a second serum creatinine value indicating a decrease to a value less than twice the baseline value (or below the Upper Limit of Normal) on a date after the event date in question B1.

a. Collection Date	b. Units	c. Results	d. Upper Limit of Normal
DD-MMM-YYYY	◯ mg/dl ◯ µmol/L		

B4. Did the subject require renal replacement therapy?
◯ Dialysis
◯ Transplant
◯ Neither

B5. Is there a reversible cause of renal failure? ◯ Yes ◯ No

a. Specify the reversible cause of renal failure

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

SECTION B: MYOCARDIAL INFARCTION (MI)

B1. Event Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Did the subject experience ischemic symptoms ≥ 10 minutes that the investigator determines are secondary to myocardial ischemia: ☐1 YES ☐0 NO ☐-8 UNKNOWN

B3. Were there **new** ECG changes consistent with infarction that can be documented in two or more contiguous leads: ☐1 YES ☐0 NO **(B4)** ☐-8 UNKNOWN **(B4)**

a. If YES, specify ECG Changes:_____

_____

B4. Were cardiac markers (CK, CKMB or Troponin) drawn in association with this event: ☐1 YES ☐0 NO **(B9)**

	a.	b.	c.	d.	e.
	Check if Not Done	**Unit Codes 1 = μg/L, ng/ml 2 = U/L, IU/L, mU/mL, MIU/mL**	**Result**	**Lower Limit**	**Upper Limit**
B5. CK	☐				
B6. CK-MB	☐				
B7. Troponin I	☐				
B8. Troponin T	☐				

SECTION B: MYOCARDIAL INFARCTION (MI) (continued)

B9. Was the event thought to have occurred in the setting of a coronary revascularization procedure: ☐1 YES ☐0 NO **(END)**

B10. If this event occurred within the setting of a coronary revascularization, is there documentation of new wall motion abnormality other than septal: ☐1 YES ☐0 NO

If YES, please provide the ECHO report.

SECTION C: REQUIRED DOCUMENTS

Below are the required documents. Please forward to NERI.

Discharge Summary/Physician Narrative

Cardiac Marker (CK, CKMB, Troponin) Lab Reports

Two comparative ECGs labeled with date and time showing changes associated with this event (if ECG changes seen in association with this event)

Treatment Of Preserved Cardiac function heart failure with an Aldosterone anTagonist

T022 Myocardial Infarction

SECTION A: GENERAL INFORMATION

A1. Subject ID:

A2. Subject Initials:

SECTION B: MYOCARDIAL INFARCTION (MI)

B1. Event date: DD-MMM-YYYY

B2. Did the subject experience ischemic symptoms ≥ 10 minutes that the investigator determines are secondary to myocardial ischemia: Yes No Unknown

B3. Were there new ECG changes consistent with infarction that can be documented in two or more contiguous leads: Yes No Unknown

a. If YES, specify ECG Changes

B4. Were cardiac markers (CK, CKMB or Troponin) drawn in association with this event: Yes No

B5. Was the event thought to have occurred in the setting of a coronary revascularization procedure: Yes No

B6. If this event occurred within the setting of a coronary revascularization, is there documentation of new wall motion abnormality other than septal: Yes No

If YES, please provide the ECHO report.

ELECTRONIC SIGNATURE

This form has not been signed.

New Onset Diabetes Mellitus

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

SECTION B: NEW ONSET DIABETES MELLITUS

B1. Event Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Please select the ADA (American Diabetes Association) criteria met for diagnosing diabetes: (check all that apply)

- ☐ NONE **(B5)**
- ☐ FASTING GLUCOSE ≥ 126 mg/dl CONFIRMED BY REPEAT LAB ON A DIFFERENT DAY
- ☐ RANDOM (NON-FASTING) GLUCOSE ≥ 200 mg/dL CONFIRMED BY FASTING GLUCOSE ≥ 126 mg/dL
- ☐ 2-HOUR POST-LOAD GLUCOSE ≥ 200 mg/dL AFTER ORAL GLUCOSE TOLERANCE TEST WITH EQUIVALENT OF 75 GRAMS OF GLUCOSE IN ADDITION TO EITHER A RANDOM GLUCOSE ≥ 200 mg/dL OR FASTING GLUCOSE ≥126 mg/dL ON A DIFFERENT DAY

Please provide the results of the 2 follow-up lab tests documenting the above criteria.

B3a. Collection date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

	UNITS	RESULT
B3b. Blood glucose result:	☐1 mg/dL ☐2 mmol/L	__ __ __. __

B4a. Collection date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

	UNITS	RESULT
B4b. Blood glucose result:	☐1 mg/dL ☐2 mmol/L	__ __ __. __

SECTION B: NEW ONSET DIABETES MELLITUS (continued)

B5. Was the subject started on medication, oral hypoglycemic agents or insulin therapy: ☐1 YES ☐0 NO **(END)**

B6. Date medication started: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B7. Type of medication:

	a. MEDICATION	b. DOSE	c. UNITS	d. FREQUENCY
1.				
2.				
3.				

SECTION C: REQUIRED DOCUMENTS

Below are the required documents. Please forward to NERI.

Discharge Summary/Physician Narrative

Lab Report of Baseline Glucose

Lab Report of two follow-up abnormal fasting and/or random glucose values

Clinical note documenting initiation of treatment for Diabetes Mellitus (insulin or oral hypoglycemics)

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

SECTION B: STROKE

B1. Event Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Identify the signs and symptoms associated with the event: (check all that apply)

- ☐ APHASIA
- ☐ ALTERED SENSATION/SENSORY DEFICIT
- ☐ FOCAL MOTOR WEAKNESS
- ☐ OTHER

1. If OTHER, specify:_____

B3. Was there a sudden onset of symptoms: ☐1 YES ☐0 NO ☐-8 UNKNOWN

B4. How long did the symptoms persist:

- ☐1 < 24 HOURS
- ☐2 24 – 72 HOURS
- ☐3 > 72 HOURS
- ☐-8 UNKNOWN

B5. Was there any readily identifiable cause other than stroke for the above symptoms (e.g. trauma, brain tumor): ☐1 YES ☐0 NO **(B6)** ☐-8 UNKNOWN **(B6)**

a. If YES, specify:_____

B6. Is there documentation of a brain infarct or hemorrhage: ☐1 YES ☐0 NO **(B8)** ☐-8 UNKNOWN **(B8)**

SECTION B: STROKE (continued)

B7. How was the brain infarct or hemorrhage documented:

- ☐ 1 CT SCAN
- ☐ 2 MRI
- ☐ 99 OTHER
  - a. If OTHER, specify:_____

B8. Was the subject seen by a neurologist or neurosurgeon:

☐ 1 YES ☐ 0 NO **(END)** ☐ -8 UNKNOWN **(END)**

B9. What diagnosis was made by the neurologist or neurosurgeon:

- ☐ 1 STROKE
- ☐ 2 TRANSIENT ISCHEMIC ATTACK (TIA)
- ☐ 99 OTHER
  - a. If OTHER, specify:_____

SECTION C: REQUIRED DOCUMENTS

Below are the required documents. Please forward to NERI.

Discharge Summary / Physician Narrative

Imaging reports

Neurology Consult Notes

New Onset Atrial Fibrillation

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

SECTION B: NEW ONSET ATRIAL FIBRILLATION

B1. Event Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Was atrial fibrillation documented on a 12-lead electrocardiogram? ☐1 YES ☐0 NO **(B3)**

a. If **YES**, is there any prior history of atrial fibrillation?

☐1 YES ☐0 NO **(B3)**

b. If **YES**, please categorize the history of atrial fibrillation?

☐1 PAROXYSMAL

☐2 PERSISTENT

☐-8 UNKNOWN

B3. Was the subject in atrial fibrillation at the time of randomization in TOPCAT? ☐1 YES ☐0 NO

SECTION C: REQUIRED DOCUMENTS

Below are the required documents. Please forward to NERI.

Discharge Summary/Physician Narrative

12-Lead Baseline ECG (prior to AF onset)

12-Lead ECG documenting AF event

Aborted Cardiac Arrest or Hospitalization for Ventricular Tachycardia

T026

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

SECTION B: ABORTED CARDIAC ARREST OR HOSPITALIZTION FOR THE MANAGEMENT OF VENTRICULAR TACHYCARDIA

B1. Event Date: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Did the subject suffer a loss of consciousness due to cardiac arrest (excluding transient losses of consciousness due to seizure or vasovagal (fainting) episodes)?

☐ 1 YES ☐ 0 NO ☐ -8 UNKNOWN

B3. Check all resuscitative efforts that were used in association with the event:

☐ CARDIOPULMONARY RESUSCITATION (CPR) ☐ UNKNOWN

☐ CARDIAC DEFIBRILLATION/CARDIOVERSION ☐ OTHER

1. Specify:_____

B4. Which of the following best describe the subject's status:
(check only one)

☐ 1 THE SUBJECT WAS RESUSCITATED (i.e. CIRCULATION WAS RESTORED) BUT DID NOT REGAIN CONSCIOUSNESS AND LATER DIED **(END)**

☐ 2 THE SUBJECT WAS RESUSCITATED, REGAINED CONSCIOUSNESS AND SURVIVED THE EVENT

☐ 3 THE SUBJECT HAD DOCUMENTED VENTRICULAR TACHYCARDIA THAT REQUIRED HOSPITALIZATION, BUT DID NOT REQUIRE URGENT RESUSCITATION.

a. Disposition after resuscitation:

☐ 1 DISCHARGED HOME

☐ 2 TRANSFERRED TO ANOTHER FACILITY

☐ 3 SUBSEQUENTLY DIED DURING SAME HOSPITALIZATION

☐ 99 OTHER

1. Specify:_____

SECTION C: REQUIRED DOCUMENTS

Below are the required documents. Please forward to NERI.

Discharge Summary/Physician Narrative
Documentation of arrest, resuscitation, and status after event
Emergency Room Records
Ambulance Records
12-Lead ECG documenting event (in cases of hospitalization for ventricular tachycardia)

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

SECTION B: HOSPITALIZATION

B1. Date of hospitalization: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Is subject still hospitalized? ☐1 YES **(B4)** ☐0 NO

B3. Date of Death/Hospital Discharge: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B4. Investigators assessment of primary reason for hospitalization:

☐1 CARDIOVASCULAR **(B5a)** ☐2 NON-CARDIOVASCULAR **(B5b)**

B5a. CV Hospitalization (select one):

☐1 DEATH
☐2 MYOCARDIAL INFARCTION
☐3 STROKE
☐4 CONGESTIVE HEART FAILURE
☐5 ABORTED CARDIAC ARREST
☐6 ARRHYTHMIA
☐7 PULMONARY EMBOLISM
☐8 CV PROCEDURE-RELATED
1. Specify:_____
☐99 OTHER CARDIOVASCULAR
2. Specify:_____

B5b. Non- CV Hospitalization (select one):

☐1 HYPERKALEMIA
☐2 RENAL FAILURE
☐3 PULMONARY
☐4 GASTROINTESTINAL
☐5 CANCER
☐99 OTHER NON-CARDIOVASCULAR
1. Specify:_____

SECTION B: HOSPITALIZATION (continued)

B6. Other major **cardiovascular** events during this hospitalization: **(check all that apply)**

- ☐ NONE **(B7)**
- ☐ DEATH
- ☐ MYOCARDIAL INFARCTION
- ☐ STROKE
- ☐ CONGESTIVE HEART FAILURE
- ☐ ABORTED CARDIAC ARREST
- ☐ ARRHYTHMIA
- ☐ PULMONARY EMBOLISM
- ☐ CV PROCEDURE-RELATED
  1. If OTHER specify: _____
- ☐ OTHER CARDIOVASCULAR EVENT
  1. If OTHER specify: _____

B7. Other major **non-cardiovascular** events during this hospitalization: **(check all that apply)**

- ☐ NONE **(B8)**
- ☐ HYPERKALEMIA
- ☐ RENAL FAILURE
- ☐ PULMONARY
- ☐ GASTROINTESTINAL
- ☐ CANCER
- ☐ OTHER NON-CARDIOVASCULAR EVENT
  1. If OTHER specify: _____

B8. Comments:_____

_____

_____

End of Study Report

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: END OF STUDY

SECTION B: END OF STUDY REPORT

B1. Study end date: __ __ - __ __ __ - __ __ __ __
D D / M M M / Y Y Y Y

B2. Primary reason subject ended the study:

☐1 STUDY COMPLETED

☐2 SUBJECT NOT RANDOMIZED

☐3 SUBJECT DECISION TO WITHDRAW

☐4 PHYSICIAN DECISION TO WITHDRAW SUBJECT

☐5 LOST TO FOLLOW-UP

☐6 DEATH **(If YES, please complete Death Report form)**

☐7 HEART TRANSPLANT

☐99 OTHER

a. If OTHER, specify: _____

B3. What is the last study visit the subject completed:

☐1 BASELINE

☐2 WEEK 4

☐3 WEEK 8

☐4 MONTH 4

SECTION B: END OF STUDY REPORT (continued)

☐5 MONTH 8

☐6 MONTH 12

☐7 MONTH 18

☐8 MONTH 24

☐9 MONTH 30

☐10 MONTH 36

☐11 MONTH 42

☐12 MONTH 48

☐13 MONTH 54

B4. Comment: _____

_____

_____

End of Study Report

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: END OF STUDY

SECTION B: END OF STUDY REPORT

B1. Study end date: __ __ - __ __ __ - __ __ __ __
D D / M M M / Y Y Y Y

B2. Primary reason subject ended the study:

☐1 STUDY COMPLETED

☐2 SUBJECT NOT RANDOMIZED

☐3 SUBJECT DECISION TO WITHDRAW

☐4 PHYSICIAN DECISION TO WITHDRAW SUBJECT

☐5 LOST TO FOLLOW-UP

☐6 DEATH **(If YES, please complete Death Report form)**

☐7 HEART TRANSPLANT

☐99 OTHER

a. If OTHER, specify: _____

SECTION B: END OF STUDY REPORT (continued)

B3. What is the last study visit the subject completed:

- ☐1 BASELINE
- ☐2 WEEK 4
- ☐3 WEEK 8
- ☐4 MONTH 4
- ☐5 MONTH 8
- ☐6 MONTH 12
- ☐7 MONTH 18
- ☐8 MONTH 24
- ☐9 MONTH 30
- ☐10 MONTH 36
- ☐11 MONTH 42
- ☐12 MONTH 48
- ☐13 MONTH 54

B4. Comment: _____

_____

_____

SECTION C: FINAL DRUG ACCOUNTABILITY

Complete this section if Study End Date did not occur on a Visit Date.

C1. Were study drug bottles returned at study end? ☐1 YES ☐0 NO **(C6)**

C2. How many unopened bottles were returned at study end? ____ ____

a. How many unopened bottles were reported as lost or thrown away by subject since the last visit? ____ ____

C3. How many empty bottles were returned at study end? ____ ____

b. How many empty bottles were reported as lost or thrown away by subject since the last visit? ____ ____

C4. How many opened bottles were returned? ____ ____ **(If zero, go to C6)**

If tablets were measured, please provide volume. If tablets were counted, please provide number.

C5. Please indicate the volume or number of residual tablets measured per opened bottle:

a.	Bottle 1:	☐1 mL	☐2 tablets	___ ___ ___
b.	Bottle 2:	☐1 mL	☐2 tablets	___ ___ ___
c.	Bottle 3:	☐1 mL	☐2 tablets	___ ___ ___
d.	Bottle 4:	☐1 mL	☐2 tablets	___ ___ ___
e.	Bottle 5:	☐1 mL	☐2 tablets	___ ___ ___

C6. Was study drug permanently discontinued since the last visit? ☐1 YES ☐0 NO **(END)**

C7. What was the date of **permanent discontinuation**: __ __/ __ __ __/ __ __ __ __
D D / M M M / Y Y Y Y

SECTION C: FINAL DRUG ACCOUNTABILITY (continued)

C8. Reason for **permanent discontinuation**:

	YES	NO
a. Persistent hyperkalemia (potassium ≥ 6.0 mmol/L)	☐1	☐0
b. Potassium ≥ 5.5 mmol/L and subject was on lowest dose of study drug	☐1	☐0
c. Abnormal renal function	☐1	☐0
d. Anaphylactoid reaction or intolerance	☐1	☐0
e. Breast tenderness or enlargement	☐1	☐0
f. Open label use of any aldosterone antagonist or potassium-sparing diuretic	☐1	☐0
g. Other	☐1	☐0

1. If Other, specify: _____

Treatment Of Preserved Cardiac function heart failure with an Aldosterone anTagonist

T030 End of Study Report
Ver. C

SECTION A: GENERAL INFORMATION

A1. Subject ID:

A2. Subject initials:

A3. Visit: End of Study

SECTION B: END OF STUDY REPORT

B1. Study end date: DD-MMM-YYYY

B2. Did the subject provide consent for the additional study visits (60 Month, 66 Month, and 72 Month visits)?

- Yes
- No

B3. Primary reason subject ended the study:

- STUDY COMPLETED
- SUBJECT NOT RANDOMIZED
- SUBJECT DECISION TO WITHDRAW
- PHYSICIAN DECISION TO WITHDRAW SUBJECT
- LOST TO FOLLOW-UP
- DEATH (Please complete Death Report form)
- HEART TRANSPLANT
- OTHER

a. If OTHER, specify:

B4. What is the last study visit the subject completed:

- BASELINE
- 4 WEEK
- 8 WEEK
- 4 MONTH
- 8 MONTH
- 12 MONTH
- 18 MONTH
- 24 MONTH
- 30 MONTH
- 36 MONTH
- 42 MONTH
- 48 MONTH
- 54 MONTH
- 60 MONTH
- 66 MONTH
- 72 MONTH

B5. Comment:

SECTION C: FINAL DRUG ACCOUNTABILITY

C1. Were study drug bottles returned at study end? ☐ YES ☐ NO

a. How many unopened bottles were returned at study end? ☐

Please indicate the allocation code and lot number for each unopened bottle that was returned to the site:

	Bottle #	Treatment Allocation Code	Lot Number
a.	1	☐	☐
b.	2	☐	☐
c.	3	☐	☐
d.	4	☐	☐
e.	5	☐	☐

C2. How many opened bottles (including empty bottles) were returned? ☐

Please indicate the treatment allocation code and lot number as well as the volume or number of residual tablets measured per opened bottle (including empty bottles):

	Bottle #	Treatment Allocation Code	Lot Number	Units	Number
a.	1	☐	☐	☐ mL ☐ tablets	☐
b.	2	☐	☐	☐ mL ☐ tablets	☐
c.	3	☐	☐	☐ mL ☐ tablets	☐
d.	4	☐	☐	☐ mL ☐ tablets	☐
e.	5	☐	☐	☐ mL ☐ tablets	☐

C3. How many unopened bottles were reported as lost or thrown away by subject since the last visit? ☐

C4. How many opened bottles (including empty bottles) were reported as lost or thrown away by subject since the last visit?

C5. Was study drug permanently discontinued? ( ) Yes ( ) No

C6. What was the date of permanent discontinuation?
DD-MMM-YYYY

C7. Reason for permanent discontinuation:	YES	NO
a. Persistent hyperkalemia (potassium ≥ 6.0 mmol/L)	( )	( )
b. Potassium ≥ 5.5 mmol/L and subject was on lowest dose of study drug	( )	( )
c. Abnormal renal function	( )	( )
d. Anaphylactoid reaction or intolerance	( )	( )
e. Breast tenderness or enlargement	( )	( )
f. Open label use of any aldosterone antagonist or potassium-sparing diuretic	( )	( )
g. Other	( )	( )

1. if Other, Specify:

ELECTRONIC SIGNATURE

This form has not been signed.

Death Report

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

SECTION B: DEATH INFORMATION

B1. Date of death: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

B2. Location of death:
(select one)

- ☐1 HOME
- ☐2 WORK
- ☐3 HOSPITAL
- ☐-8 UNKNOWN **(B4)**
- ☐99 OTHER
  - a. If OTHER, specify:_____

B3. Please indicate the place of death:

- a. City: _____
- b. State or Province: _____
- c. Country _____

B4. Investigator's assessment of primary cause of death: (select one)

- ☐1 CARDIOVASCULAR DEATH **(B5a)**
- ☐2 NON-CARDIOVASCULAR DEATH **(B5b)**
- ☐-8 UNKNOWN **(B6)**

B5a. Cardiovascular Death (select one): **(B6)**

- ☐1 MYOCARDIAL INFARCTION
- ☐2 PUMP FAILURE
- ☐3 SUDDEN DEATH: WITNESSED
- ☐4 SUDDEN DEATH: LAST SEEN ≥ 1 hr and < 24 hrs.
- ☐5 STROKE
- ☐6 PULMONARY EMBOLISM
- ☐7 CV PROCEDURE-RELATED
  - 1. Specify:_____
- ☐8 OTHER CARDIOVASCULAR
  - 2. Specify:_____

B5b. Non-Cardiovascular Death (select one):

- ☐1 RENAL
- ☐2 PULMONARY
- ☐3 MALIGNANCY
- ☐4 INFECTION
- ☐5 HEPATOBILIARY
- ☐6 GI
- ☐7 ACCIDENTAL
- ☐8 SUICIDE
- ☐9 NON-CV PROCEDURE-RELATED
  - 1. Specify:_____
- ☐10 OTHER NON-CARDIOVASCULAR
  - 2. Specify:_____

SECTION B: DEATH INFORMATION (continued)

B6. Provide a brief description of the events leading up to subject's death:

_____

_____

_____

_____

_____

_____

_____

B7. Considering the subject's condition prior to death, was the death clinically expected: ☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN

B8. Was resuscitation attempted: ☐$_1$ YES ☐$_0$ NO ☐$_{-8}$ UNKNOWN

B9. Was an autopsy/post mortem performed: ☐$_1$ YES ☐$_0$ NO **(END)** ☐$_{-8}$ UNKNOWN**(END)**

a. If YES, date of autopsy: __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

b. Primary cause of death indicated on autopsy report: _____

SECTION C: REQUIRED DOCUMENTS

Below are the required documents. Please forward to NERI.

Discharge summary/Physician Narrative
Autopsy Report
ECGs (in cases of fatal myocardial infarction)
Cardiac marker lab reports (in cases of fatal myocardial infarction)

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: END OF STUDY

SECTION B: CONTACT INFORMATION

B1.	Was a successful contact made with the Subject or Subject Proxy?	☐1 YES ☐0 NO (**EOF**)
B1a.	Date of contact:	DD/MMM/YYYY
B2.	Contact made with whom:	☐1 Subject Only (**B3**)
		☐2 Subject and proxy
		☐3 Proxy only
	B2a. If Proxy involved:	☐1 Spouse
		☐2 Child
		☐3 Other relative
		☐4 Formal caregiver
		☐5 Other Non-relative
B3.	Mode of contact:	☐1 Phone
		☐2 Mail/email
		☐3 In Hospital / Clinic
B4.	Is Subject alive at the time of contact?	☐1 YES (**EOF**) ☐0 NO ☐ Unknown
B5.	Last date Subject known to be alive.	DD/MMM/YYYY

INSTRUCTIONS TO SITE COORDINATORS:
If subject status is alive or unknown and there is additional information available including data on whether additional study outcomes have occurred, initialize final study visit and enter as much information as can be obtained.

If subject is found to be deceased, enter T030 with reason = Death, enter T031: Death Report form and associated T053: SAE form.

Disclosure of Treatment Arm

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: MISCELLANEOUS VISIT

SECTION B: DISCLOSURE OF TREATMENT ARM

		YES	NO	
B1.	Was the subject told the treatment arm:	☐1	☐0	
B2.	Was a non-TOPCAT staff member told the treatment arm:	☐1	☐0	
B3.	Was a TOPCAT staff member told the treatment arm:	☐1	☐0	**(B6)**

B4. Number of TOPCAT staff told treatment arm: ____ ____

		Staff #1	Staff # 2	Staff # 3
B5.	Initials of TOPCAT staff:	____ ____ ____	____ ____ ____	____ ___ ____

B6. Reason for disclosure:

☐1 SUBJECT REQUEST

☐2 PHYSICIAN REQUEST

☐3 ERROR

☐99 OTHER

a. If OTHER, specify:_____

B7. Provide a brief description of how and/or why the disclosure occurred.

_____

_____

_____

B8. Disclosure date: __ __ - __ __ __ - __ __ __ __
D D / M M M / Y Y Y Y

Adverse Event Form

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: ADVERSE EVENTS

SECTION B: INITIAL OR FOLLOW-UP AE

B1. Is this an initial or follow-up AE report? ☐1 Initial ☐2 Follow-up

B2. AE identification number* ____ ____

**For Follow-up event enter the ID number of originally reported AE*

SECTION C: ADVERSE EVENT

C1. AE Term _____

C2. Primary category (select one)

☐1 Auditory/ocular
☐2 Cancer
☐3 Cardiovascular
☐4 Endocrine and metabolic
☐5 Gastrointestinal
☐6 Hematological
☐7 Hepatobiliary/pancreas
☐8 Infection
☐9 Musculoskeletal/skin
☐10 Neurological/psychiatric
☐11 Pulmonary/upper respiratory
☐12 Renal/genitourinary
☐13 Sexual/reproductive function
☐14 Vascular (non-cardiac)
☐15 Other
a. Specify: _____

C3. Onset date __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

C4. Outcome
☐1 Resolved no sequelae
☐2 Resolved with sequelae
☐3 Ongoing **(C6)**
☐4 Death **(C5b)**

C5a. Resolution date __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

C5b. Death date __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

C6. Severity

- ☐ 1 Mild
- ☐ 2 Moderate
- ☐ 3 Severe
- ☐ 4 Life-threatening

C7. Relationship to study drug

- ☐ 1 Unrelated
- ☐ 2 Possible
- ☐ 3 Probable
- ☐ 4 Definite

C8. Action taken (check all that apply)

- ☐ None **(C9)**
- ☐ Medical
- ☐ Surgical
- ☐ Other

a. Specify _____

C9. Is this a serious adverse event (SAE)? ☐ 1 Yes ☐ 0 No

** If Yes, than a separate SAE form must be completed*

C10. Comments: _____

_____

_____

_____

Adverse Event Form

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: ADVERSE EVENTS

SECTION B: INITIAL OR FOLLOW-UP AE

B1. Is this an initial or follow-up AE report? ☐1 Initial ☐2 Follow-up

B2. AE identification number* ____ ____

**For Follow-up event enter the ID number of originally reported AE*

B3. Does this adverse event represent any a new study endpoint in any of the following categories? (If Yes, select one category) ☐1 Yes ☐0 No

- ☐1 Hospitalization for the management of heart failure
- ☐2 New onset of diabetes mellitus
- ☐3 New onset of atrial fibrillation
- ☐4 Myocardial infarction or cardiac marker elevation
- ☐5 Stroke
- ☐6 Deterioration of renal function
- ☐7 Aborted cardiac arrest or hospitalization for the management of ventricular tachycardia

SECTION C: ADVERSE EVENT

C1. AE Term _____

C2. Primary category (select one)

- ☐1 Auditory/ocular
- ☐2 Cancer
- ☐3 Cardiovascular
- ☐4 Endocrine and metabolic
- ☐5 Gastrointestinal
- ☐6 Hematological
- ☐7 Hepatobiliary/pancreas
- ☐8 Infection
- ☐9 Musculoskeletal/skin
- ☐10 Neurological/psychiatric
- ☐11 Pulmonary/upper respiratory
- ☐12 Renal/genitourinary
- ☐13 Sexual/reproductive function
- ☐14 Vascular (non-cardiac)
- ☐15 Other
  - a. Specify: _____

SECTION C: ADVERSE EVENT (Continued)

C3. Onset date __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

C4. Outcome
☐1 Resolved no sequelae
☐2 Resolved with sequelae
☐3 Ongoing **(C6)**
☐4 Death **(C5b)**

C5a. Resolution date __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

C5b. Death date __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

C6. Severity
☐1 Mild
☐2 Moderate
☐3 Severe
☐4 Life-threatening

C7. Relationship to study drug
☐1 Unrelated
☐2 Possible
☐3 Probable
☐4 Definite

C8. Action taken (check all that apply)
☐ None **(C9)**
☐ Medical
☐ Surgical
☐ Other

a. Specify _____

C9. Is this a serious adverse event (SAE)? ☐1 Yes ☐0 No
** If Yes, than a separate SAE form must be completed*

C10. Comments:
_____

_____

_____

_____

Serious Adverse Event Form

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: ADVERSE EVENTS

A4. Date of Report __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

A5. Date of Birth __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

A6. Gender ☐1 Male ☐2 Female

SECTION B: INITIAL OR FOLLOW-UP SAE

B1. Is this an initial or follow-up SAE report? ☐1 Initial ☐2 Follow-up

B2. AE reference number* ___ ___

**Enter the ID number of originally reported AE*

B3. Date Investigator first learned about AE __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

SECTION C: SERIOUS ADVERSE EVENT

C1. AE Term _____

C2. Onset date __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

C3. SAE Category (check all that apply)

- ☐ Unanticipated Adverse Drug Effect (UADE)
- ☐ Death *(Provide Death Certificate, when available)*
- ☐ Life-Threatening
- ☐ Persistent/ Significant Disability
- ☐ Initial or Prolonged Hospitalization *(Provide initial H&P and discharge summary, when available)*
- ☐ Congenital Anomaly/Birth Defect
- ☐ Permanent impairment/damage of a body function/structure
- ☐ Intervention to prevent permanent impairment of a body function/structure

C4. Outcome

- ☐1 Resolved no sequelae
- ☐2 Resolved with sequelae
- ☐3 Ongoing **(C5)**
- ☐4 Death **(C4b)**

C4a. Resolution date __ __ - __ __ __ - __ __ __ __ **(C5)**
D D - M M M - Y Y Y Y

C4b. Death date __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

C5. Was subject withdrawn from the study? ☐1 Yes ☐0 No

SECTION D: STUDY DRUG INFORMATION

D1. Study Drug Treatment (Blinded)

	a. Treatment Allocation Code	b. Total Daily Dose	c. Start Date (dd-mmm-yyyy)	d. Continuing this dose	e. Stop Date (dd-mmm-yyyy)
1.		☐0 0 mg ☐1 15 mg ☐2 30 mg ☐3 45 mg		☐	
2.		☐0 0 mg ☐1 15 mg ☐2 30 mg ☐3 45 mg		☐	
3.		☐0 0 mg ☐1 15 mg ☐2 30 mg ☐3 45 mg		☐	
4.		☐0 0 mg ☐1 15 mg ☐2 30 mg ☐3 45 mg		☐	
5.		☐0 0 mg ☐1 15 mg ☐2 30 mg ☐3 45 mg		☐	

D2. Relationship to Study Drug
- ☐1 Definite
- ☐2 Probable
- ☐3 Possible
- ☐4 Unrelated

D3. Action Taken
- ☐1 No change in study drug
- ☐2 Study drug dose reduced
- ☐3 Study drug dose stopped, temporarily
- ☐4 Study drug dose stopped, permanently

SECTION E: SYMPTOMS, TREATMENT, DIAGNOSTIC TESTS

E1. SAE Descriptive Narrative (Brief chronological summary of symptoms, treatment, diagnosis, autopsy finding):

E2. Are there Relevant Diagnostic Test/ Laboratory Data to report? ☐1 YES ☐0 NO **(E3)**

	a. Test	b. Results	c. Units
1.			
2.			
3.			
4.			
5.			

E3. Are there Relevant pre-existing medical conditions to report? ☐1 YES ☐0 NO **(E4)**

E3a. _____

_____

_____

_____

E4. Are there concomitant medications to report? ☐1 YES ☐0 NO **(E5)**

	a. Medication	b. Dose	c. Units*	d. Frequency**
1.				
2.				
3.				
4.				
5.				

***Unit Codes: Mg=1, G=2, Ml=3, Puff=4, Other=99**
****Frequency Codes: Once a day=1, Twice a day=2, Three times a day=3, Every other day=4, As needed=5, Other=99**

E5. Other Comments

_____

_____

_____

PI Signature: _____ __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

Serious Adverse Event Form

SECTION A: GENERAL INFORMATION

A1. Subject ID: ___ ___ ___ ___ - ___ ___ ___ - ___

A2. Subject initials: ___ ___ ___

A3. Visit: ADVERSE EVENTS

A4. Date of Report __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

A5. Date of Birth __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

A6. Gender ☐1 Male ☐2 Female

SECTION B: INITIAL OR FOLLOW-UP SAE

B1. Is this an initial or follow-up SAE report? ☐1 Initial ☐2 Follow-up

B2. AE reference number* ___ ___

**Enter the ID number of originally reported AE*

B3. Date Investigator first learned about AE __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

SECTION C: SERIOUS ADVERSE EVENT

C1. AE Term _____

C2. Onset date __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

C3. SAE Category (check all that apply)

- ☐ Unanticipated Adverse Drug Effect (UADE)
- ☐ Death *(Provide Death Certificate, when available)*
- ☐ Life-Threatening
- ☐ Persistent/ Significant Disability
- ☐ Initial Hospitalization *(Provide initial H&P and discharge summary, when available)*
- ☐ Prolonged Hospitalization *(Provide initial H&P and discharge summary, when available)*
- ☐ Congenital Anomaly/Birth Defect
- ☐ Permanent impairment/damage of a body function/structure
- ☐ Intervention to prevent permanent impairment of a body function/structure

C4a. Resolution date __ __ - __ __ __ - __ __ __ __ **(C5)**
D D - M M M - Y Y Y Y

C4b. Death date __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

C5. Was subject withdrawn from the study? ☐1 Yes ☐0 No

C4. Outcome
☐1 Resolved no sequelae
☐2 Resolved with sequelae
☐3 Ongoing **(C5)**
☐4 Death **(C4b)**

SECTION D: STUDY DRUG INFORMATION

D1. Study Drug Treatment (Blinded)

	a. Treatment Allocation Code	b. Total Daily Dose	c. Start Date (dd-mmm-yyyy)	d. Continuing this dose	e. Stop Date (dd-mmm-yyyy)
1.		☐0 0 mg ☐1 15 mg ☐2 30 mg ☐3 45 mg		☐	
2.		☐0 0 mg ☐1 15 mg ☐2 30 mg ☐3 45 mg		☐	
3.		☐0 0 mg ☐1 15 mg ☐2 30 mg ☐3 45 mg		☐	
4.		☐0 0 mg ☐1 15 mg ☐2 30 mg ☐3 45 mg		☐	
5.		☐0 0 mg ☐1 15 mg ☐2 30 mg ☐3 45 mg		☐	

D2. Relationship to Study Drug
☐1 Definite
☐2 Probable
☐3 Possible
☐4 Unrelated

D3. Action Taken
☐1 No change in study drug
☐2 Study drug dose reduced
☐3 Study drug dose stopped, temporarily
☐4 Study drug dose stopped, permanently

SECTION E: SYMPTOMS, TREATMENT, DIAGNOSTIC TESTS

E1. SAE Descriptive Narrative (Brief chronological summary of symptoms, treatment, diagnosis, autopsy finding):

E2. Are there Relevant Diagnostic Test/ Laboratory Data to report? ☐1 YES ☐0 NO **(E3)**

	a. Test	b. Results	c. Units
1.			
2.			
3.			
4.			
5.			

E3. Are there Relevant pre-existing medical conditions to report? ☐1 YES ☐0 NO **(E4)**

E3a.

E4. Are there concomitant medications to report? ☐1 YES ☐0 NO **(E5)**

	a. Medication	b. Dose	c. Units*	d. Frequency**
1.				
2.				
3.				
4.				
5.				

***Unit Codes: Mg=1, G=2, Ml=3, Puff=4, Other=99**
****Frequency Codes: Once a day=1, Twice a day=2, Three times a day=3, Every other day=4, As needed=5, Other=99**

E5. Other Comments

PI Signature: _____ __ __ - __ __ __ - __ __ __ __
D D - M M M - Y Y Y Y

Treatment Of Preserved Cardiac function heart failure with an Aldosterone anTagonist

T053 Adverse Event / Serious Adverse Event
T053 Version: A

SECTION A: GENERAL INFORMATION

A1. Subject ID:

A2. Subject Initials:

A3. Visit:

A4. Date of report:
DD-MMM-YYYY

SECTION B: INITIAL OR FOLLOW-UP

B1. Is this an initial or follow-up adverse event report?
Initial Follow-up

B2. Adverse event identification number:

B3. Date Investigator first learned about adverse event:
DD-MMM-YYYY

B4. Does this adverse event represent a new study end point in any of the following categories?
Yes No

a.
- Hospitalization for the management of heart failure
- New onset of diabetes mellitus
- New onset of atrial fibrillation
- Myocardial infarction or cardiac marker elevation
- Stroke
- Deterioration of renal function
- Aborted cardiac arrest or hospitalization for the management of ventricular tachycardia
- Transient Ischemic Attack (TIA)
- Unstable angina

SECTION C: ADVERSE EVENT

C1. Adverse event term:

C2. Primary category:
- Auditory/ocular
- Cancer
- Cardiovascular
- Endocrine and metabolic
- Gastrointestinal
- Hematological
- Hepatobiliary/pancreas
- Infection
- Musculoskeletal/skin
- Neurological/psychiatric
- Pulmonary/upper respiratory
- Renal/genitourinary
- Sexual/reproductive function
- Vascular (non-cardiac)
- Other

a. Specify:

C3. Onset date:

DD-MMM-YYYY

C4. Outcome:

- Resolved no sequelae
- Resolved with sequelae
- Ongoing
- Death

a. Resolution date:

DD-MMM-YYYY

b. Death date:

DD-MMM-YYYY

C5. Severity:

- Mild
- Moderate
- Severe
- Life-threatening

C6. Relationship to study drug:

- Definite
- Probable
- Possible
- Unrelated

C7. Action taken (check all that apply):

a. None

b. Medical

c. Surgical

d. Other

1. Specify:

C8. Is this a serious adverse event (SAE)? Yes No

C9. Was the subject withdrawn from participating in the study? Yes No

C10. SAE Category: (check all that apply)

- Unanticipated Adverse Drug Effect (UADE)
- Death
- Life-Threatening
- Persistent/ Significant Disability
- Initial Hospitalization
- Prolonged Hospitalization
- Congenital Anomaly/Birth Defect
- Permanent impairment/damage of a body function/structure
- Intervention to prevent permanent impairment of a body function/structure

SECTION D: STUDY DRUG INFORMATION

D1. Study drug information at onset of event

a. Treatment allocation code at the event onset:

b. Total daily dose at the event onset:

- 0 mg
- 15 mg
- 30 mg
- 45 mg

c. Most recent start date of the study drug dose during event onset:

DD-MMM-YYYY

D2. Action taken:

- No change in study drug
- Study drug dose reduced
- Study drug stopped, temporarily
- Study drug stopped, permanently

SECTION E: SYMPTOMS,TREATMENT, DIAGNOSTIC TEST

E1. SAE descriptive narrative:

E2. Are there relevant diagnostic test(s) &/or laboratory data to report?

- Yes
- No

	a. Test	b. Results	c. Units
1.			

E3. Are there relevant pre-existing medical conditions to report?

- Yes
- No

a. Specify:

E4. Are there concomitant medications to report?

- Yes
- No

a. Current concomitant medications:
(Imported from the most recent T007 medications form;update as necessary)

SECTION F: COMMENTS

F1. Comments:

ELECTRONIC SIGNATURE

This form has not been signed.

TOPCAT
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Hospitalization for Worsening Congestive Heart Failure Adjudication Form	Patient #:_____ Site #:_____Pt. Initials:_____ Unique Event #:_____	Site Reported Date: _ _ / _ _ _ / _ _ _ _ Day Month Year

1.) Unexpected presentation to acute care facility requiring overnight hospitalization?

☐1 Yes ☐0 No

2.) Were there symptoms of HF? ☐1 Yes ☐0 No (If Yes, check all that apply.)

☐ Increasing dyspnea on exertion
☐ Worsening orthopnea
☐ Paroxysmal nocturnal dyspnea
☐ Increasing fatigue/decreasing exercise tolerance
☐ Altered mental state
☐ Other:_____

3.) Were there signs of HF? ☐1 Yes ☐0 No (If Yes, check all that apply.)

☐ Peripheral edema
☐ Elevated jugular venous pressure
☐ Radiological signs of heart failure
☐ Increasing abdominal distension or ascites
☐ Pulmonary edema or rales
☐ Rapid weight gain
☐ Hepatojugular reflux
☐ S3 Gallop
☐ Elevated BNP or N-Terminal pro-BNP
☐ Other: _____

4.) Did patient require IV Therapy?

☐0 No ☐1 Yes (If Yes, check all that apply.)

☐ Vasodilators ☐ Diuretics ☐ Inotropes
☐ Mechanical Fluid Removal ☐ IABP

5.) TOPCAT Hospitalization for Worsening CHF met? (Select only one response)

☐1 **YES, Criteria Met (fill out date of event below)**
☐2 NO, But Worsening HF During Ongoing Hospitalization (no date)
☐0 NO, Criteria Not Met (no date)

6.) If Criteria Met, Indicate Date of Event: (Select only one response)

☐1 Site Reported Date of Event

☐2 CEC Adjudicated Date of Event _ _ / _ _ _ / _ _ _ _
Day Month Year

☐ **CEC IDENTIFIED**

Comments:_____

Physician Reviewer Signature:_____**Date** _____ / _____ / _____

CEC Administrative Signature:_____**Date** _____ / _____ / _____

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Myocardial Infarction Adjudication Form	Patient #:_____ Site #:_____Pt. Initials:_____ Unique Event #:_____	Site Reported Date: _ _ / _ _ _ / _ _ _ _ Day Month Year

1.) Clinical Presentation/ Symptoms consistent with ischemia? ☐$_1$ Yes ☐$_0$ No

2.) ECG Changes consistent with TOPCAT MI? ☐$_1$ Yes ☐$_0$ No

If Yes, check all that apply:

- ☐ New significant Q waves (or R waves in V1-V2) in two contiguous leads in the absence of previous LVH or conduction abnormalities.
- ☐ Evolving ST-segment to T-wave changes in two or more contiguous leads.
- ☐ Development of new left bundle branch block.
- ☐ ST segment elevation requiring thrombolytics or PCI.

3.) Cardiac Markers meeting TOPCAT MI criteria? ☐$_1$ Yes ☐$_0$ No

If Yes, check all that apply:

- ☐ Troponin >= 2x ULN (for necrosis)
- ☐ CKMB >= 2x ULN
- ☐ Serial CK changes of >= 2x ULN, If only CK is drawn
- ☐ Post PCI: Marker >= 3x ULN and >= 50% above last measurement, if last measure was >= ULN
- ☐ Post CABG: CKMB >= 5x ULN and >= 50% above last measurement, if last measure was >= ULN
- ☐ Post CABG:Markers were not drawn but there is clear documentation of new wall motion abnormality (other than septal) or new Q waves

4.) Were there any signs, symptoms, or treatment for HF? ☐$_1$ Yes ☐$_0$ No

5.) TOPCAT MI Criteria Met? (Select only one response)

☐$_1$ **YES, TOPCAT MI Criteria Met (fill in event date below)**
☐$_0$ NO, TOPCAT MI Criteria Not Met (no event date)

6.) If Criteria Met, Indicate Date of Event: (Select only one response)

☐$_1$ Site Reported Date of Event
☐$_2$ CEC Adjudicated Date of Event _ _ / _ _ _ / _ _ _ _
Day Month Year

☐ **CEC IDENTIFIED**

Comments:_____

Physician Reviewer Signature:_____**Date** _____ / _____ / _____

CEC Administrative Signature:_____**Date** _____ / _____ / _____

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New Onset Diabetes Mellitus Adjudication Form	Patient #:_____ Site #:_____Pt. Initials:_____ Unique Event #:_____	Site Reported Date: _ _ / _ _ _ / _ _ _ _ Day Month Year

1.) ☐ **Blood glucose meeting ADA criteria for diabetes (check all that apply):**

☐ Two FBS on separate days ≥ 126mg/dl

☐ Random glucose ≥ 200mg/dl and subsequent FBS ≥ 126mg/dl

☐ 2-hour post-load glucose ≥ 200mg/dl after oral glucose tolerance test with an equivalent of 75 grams of glucose in addition to either a random glucose ≥ 200mg/dl or FBS ≥ 126mg/dl on a different day.

AND/OR

☐ **The initiation and use of oral hypoglycemic agents, insulin sensitizers and/or insulin therapy.**

2.) TOPCAT New Onset Diabetes Mellitus Criteria Met? (Select only one response)

☐$_1$ **YES, Criteria Met (fill in date of event below)**

☐$_0$ NO, Criteria Not Met (no date of event)

3.) If Criteria Met, Indicate Date of Event: (Select only one response)

☐$_1$ Site Reported Date of Event

☐$_2$ CEC Adjudicated Date of Event _ _ / _ _ _ / _ _ _ _
Day Month Year

☐ **CEC IDENTIFIED**

Comments:_____

Physician Reviewer Signature:_____**Date** _____ / _____ / _____

CEC Administrative Signature:_____**Date** _____ / _____ / _____

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Stroke Adjudication Form	**Patient #:**_____ **Site #:**_____**Pt. Initials:**_____ **Unique Event #:**_____	**Site Reported Date:** _ _ / _ _ _ / _ _ _ _ Day Month Year

1.) Focal neurological deficit? ☐$_1$ YES ☐$_0$ NO **If Yes, please select only one response:**

☐$_1$ Focal neurological deficit *not* reversible within 24 hours and not due to other readily identifiable cause.

OR

☐$_2$ Focal neurological deficit that *is* reversible within 24 hours and brain imaging clearly documenting a new infarction or hemorrhage.

2.) TOPCAT Stroke Criteria Met? (Select only one response)

☐$_1$ **YES, Stroke Criteria Met** *specify only one response:*

- ☐$_1$ Hemorrhagic stroke
- ☐$_2$ Non-Hemorrhagic stroke
- ☐$_{-8}$ Unknown

☐$_0$ NO, Stroke Criteria Not Met

3.) If Criteria Met, Indicate Date of Event: (Select only one response)

☐$_1$ Site Reported Date of Event

☐$_2$ CEC Adjudicated Date of Event, specify _ _ / _ _ _ / _ _ _ _
Day Month Year

☐$_1$ **CEC IDENTIFIED**

Comments:_____

Physician Reviewer Signature:_____**Date** _____ **/** _____ **/** _____

CEC Administrative Signature:_____**Date** _____ **/** _____ **/** _____

TOPCAT
Funded by the NHLBI

New Onset Atrial Fibrillation Adjudication Form	Patient #:_____ Site #:_____Pt. Initials:_____ Unique Event #:_____	Site Reported Date: _ _ / _ _ _ / _ _ _ _ Day Month Year

1.) TOPCAT New Onset Atrial Fibrillation Criteria Met? (Select only one response)

☐$_1$ **YES, Criteria Met (fill in date of event below)**

☐$_0$ NO, Criteria Not Met (no date of event)

2.) If Criteria Met, Indicate Date of Event: (Select only one response)

☐$_1$ Site Reported Date of Event

☐$_2$ CEC Adjudicated Date of Event _ _ / _ _ _ / _ _ _ _
Day Month Year

☐ **CEC IDENTIFIED**

Comments:_____

Physician Reviewer Signature:_____**Date** _____ **/** _____ **/** _____

CEC Administrative Signature:_____**Date** _____ **/** _____ **/** _____

Aborted Cardiac Arrest/VT Hospitalization Adjudication Form	Patient #:_____ Site #:_____Pt. Initials:_____ Unique Event #:_____ Select only one : ☐1 ACA ☐2 VT	Site Reported Date: _ _ / _ _ _ / _ _ _ _ Day Month Year

1.) TOPCAT Aborted Cardiac Arrest Criteria Met? (Select only one response)

☐1 **YES, Aborted Cardiac Arrest Criteria Met (fill in date of event)**
☐3 **YES, VT Hospitalization Criteria Met (fill in date of event)**
☐0 NO, Criteria Not Met (no date of event)

2.) If Criteria Met, Indicate Date of Event: (Select only one response)

☐1 Site Reported Date of Event

☐2 CEC Adjudicated Date of Event _ _ / _ _ _ / _ _ _ _
Day Month Year

☐ **CEC IDENTIFIED**

Comments:_____

Physician Reviewer Signature:_____**Date** _____ **/** _____ **/** _____

CEC Administrative Signature:_____**Date** _____ **/** _____ **/** _____

TOPCAT
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Death Adjudication Form	**Patient #:**_____ **Site #:**_____**Pt. Initials:**_____ **Unique Event #:**_____	**Site Reported Date:** _ _ / _ _ _ / _ _ _ _ Day Month Year

1.) Indicate primary cause of Death: **(Select only one response)**

☐1 CV – Cardiovascular Death
☐2 Non-CV – Non-Cardiovascular Death
☐-8 Unknown

2.) CV Death specify: (Select only one response)

☐1 Fatal Myocardial Infarction
☐2 Pump Faillure
☐3 Sudden Death, *please specify only one response::*
  ☐1 Witnessed or last seen alive < 1 hr
  ☐2 Last seen alive ≥ 1hr and < 24hrs
☐4 Presumed Sudden Death
☐5 Presumed CV Death
☐6 Fatal Stroke, *please specify only one response:*
  ☐1 Hemorrhagic
  ☐2 Non-hemorrhagic
  ☐-8 Unknown
☐7 Pulmonary Embolism
☐8 CV Procedural, *please specify only one response:*
  ☐1 CABG
  ☐2 PCI / Stenting
  ☐3 Valvular
  ☐99 Other CV Procedural, *specify:*_____
☐99 Other Cardiovascular, *specify:*_____

3.)Non-CV Death specify: (Select only one response)

☐1 Infection
☐2 Malignancy
☐3 Pulmonary
☐4 GI
☐5 Renal
☐6 Hyperkalemia
☐7 Accidental
☐8 Suicide
☐9 Diabetes
☐99 Other non-cardiovascular, *specify:*
_____

4.) Indicate Date of Death: (Select only one response)

☐1 Site Reported Date of Event

☐2 CEC Adjudicated Date of Event _ _ / _ _ _ / _ _ _ _
Day Month Year

☐ **CEC IDENTIFIED**

Comments:_____

Physician Reviewer Signature:_____**Date** _____ **/** _____ **/** _____

CEC Administrative Signature:_____**Date** _____ **/** _____ **/** _____

Treatment Of Preserved Cardiac function heart failure with an Aldosterone anTagonist

T080: Between Visit Return of Study Drug

SECTION A: GENERAL INFORMATION

A1. Subject ID:

A2. Subject Initials:

A3. Visit: Baseline

SECTION B: STUDY DRUG INFORMATION

B1. Date between visits when study drug returned

DD-MMM-YYYY

B2. Initials of person who received returned study drug

B3. How many unopened bottles were returned

Bottle label(s):	Treatment Allocation Code	Lot Number
a.		
b.		
c.		
d.		
e.		

B4. How many opened bottles were returned?

Bottle labels (s):	Treatment Allocation Code	Lot Number	Units	Number
a.			mL tablets	
b.			mL tablets	
c.			mL tablets	
d.			mL tablets	
e.			mL tablets	

Treatment Of Preserved Cardiac function heart failure with an Aldosterone anTagonist

T081: Between Visit Study Drug Dispensing

SECTION A: GENERAL INFORMATION

A1. Subject ID:

A2. Subject Initials:

A3. Visit: Baseline

SECTION B: STUDY DRUG DISTRIBUTION

B1. Was study drug dispensed between visits?

- Yes
- No

B2. Date between visits when study drug dispensed

DD-MMM-YYYY

B3. Initials of person who dispensed study drug:

B4. Number of bottles dispensed

B5. Bottle label(s):		Treatment Allocation Code	Lot Number
	a.		
	b.		
	c.		
	d.		
	e.		
	f.		
	g.		
	h.		
	i.		
	j.		

B6. Was study drug returned by the subject between visits?

- Yes
- No