

## *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.

Place an **X** 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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Showering/Bathing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Walking 1 block on level ground	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Doing yardwork, housework or carrying groceries	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Climbing a flight of stairs without stopping	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hurrying or jogging (as if to catch a bus)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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<br>a week, but not<br>every day | 1-2 times a week         | Less than once a<br>week | Never over the<br>past 2 weeks |
| <input type="checkbox"/> | <input type="checkbox"/>                        | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>       |

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

It has been ...

- |                                |                                  |                                 |                               |                                 |                                       |
|--------------------------------|----------------------------------|---------------------------------|-------------------------------|---------------------------------|---------------------------------------|
| <b>Extremely</b><br>bothersome | <b>Quite a bit</b><br>bothersome | <b>Moderately</b><br>bothersome | <b>Slightly</b><br>bothersome | <b>Not at all</b><br>bothersome | I've had <b>no</b><br><b>swelling</b> |
| <input type="checkbox"/>       | <input type="checkbox"/>         | <input type="checkbox"/>        | <input type="checkbox"/>      | <input type="checkbox"/>        | <input type="checkbox"/>              |

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

- |                          |                          |                          |  |                          |                          |                                   |
|--------------------------|--------------------------|--------------------------|--|--------------------------|--------------------------|-----------------------------------|
| All of the<br>time       | Several<br>times per day | At least<br>once a day   | 3 or more times<br>per week but not<br>every day | 1-2 times<br>per week    | Less than once<br>a week | Never over<br>the past 2<br>weeks |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>          |

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

It has been ...

- |                                |                                  |                                 |                               |                                 |                               |
|--------------------------------|----------------------------------|---------------------------------|-------------------------------|---------------------------------|-------------------------------|
| <b>Extremely</b><br>bothersome | <b>Quite a bit</b><br>bothersome | <b>Moderately</b><br>bothersome | <b>Slightly</b><br>bothersome | <b>Not at all</b><br>bothersome | I've had<br><b>no fatigue</b> |
| <input type="checkbox"/>       | <input type="checkbox"/>         | <input type="checkbox"/>        | <input type="checkbox"/>      | <input type="checkbox"/>        | <input type="checkbox"/>      |

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<br>time       | Several<br>times per day | At least<br>once a day   | 3 or more times<br>per week but not<br>every day | 1-2 times<br>per week    | Less than once<br>a week | Never over<br>the past 2<br>weeks |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>                         | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/>          |

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

It has been ...

<b>Extremely</b> bothersome	<b>Quite a bit</b> bothersome	<b>Moderately</b> bothersome	<b>Slightly</b> bothersome	<b>Not at all</b> bothersome	I've had <b>no</b> <b>shortness of breath</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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?

<b>Not at all</b> sure	<b>Not very</b> sure	<b>Somewhat</b> sure	<b>Mostly</b> sure	<b>Completely</b> sure
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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

It has <b>extremely</b> limited my enjoyment of life	It has limited my enjoyment of life <b>quite a bit</b>	It has <b>moderately</b> limited my enjoyment of life	It has <b>slightly</b> limited my enjoyment of life	It has <b>not limited</b> my enjoyment of life at all
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Working or doing household chores	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Visiting family or friends out of your home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Intimate relationships with loved ones	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

# The Kansas City Cardiomyopathy Questionnaire Scoring Instructions

There are 10 summary scores within the KCCQ, which are calculated as follows:

## 1. Physical Limitation

- Code responses to each of Questions 1a-f as follows:

Extremely limited = 1

Quite a bit limited = 2

Moderately limited = 3

Slightly limited = 4

Not at all limited = 5

Limited for other reasons or did not do = *<missing value>*

- If at least three of Questions 1a-f are not missing, then compute

$$\text{Physical Limitation Score} = 100 * [(\text{mean of Questions 1a-f actually answered}) - 1] / 4$$

*(see footnote at end of this document for explanation of meaning of “actually answered”)*

## 2. Symptom Stability

- Code the response to Question 2 as follows:

Much worse = 1

Slightly worse = 2

Not changed = 3

Slightly better = 4

Much better = 5

I've had no symptoms over the last 2 weeks = 3

- If Question 2 is not missing, then compute

$$\text{Symptom Stability Score} = 100 * [( \text{Question 2} ) - 1] / 4$$

## 3. Symptom Frequency

- Code responses to Questions 3, 5, 7 and 9 as follows:

### Question 3

Every morning = 1

3 or more times a week but not every day = 2

1-2 times a week = 3

Less than once a week = 4

Never over the past 2 weeks = 5

### 3. Symptom Frequency (cont.)

#### Questions 5 and 7

All of the time = 1

Several times a day = 2

At least once a day = 3

3 or more times a week but not every day = 4

1-2 times a week = 5

Less than once a week = 6

Never over the past 2 weeks = 7

#### Question 9

Every night = 1

3 or more times a week but not every day = 2

1-2 times a week = 3

Less than once a week = 4

Never over the past 2 weeks = 5

- If at least two of Questions 3, 5, 7 and 9 are not missing, then compute:

$$S3 = [(Question\ 3) - 1]/4$$

$$S5 = [(Question\ 5) - 1]/6$$

$$S7 = [(Question\ 7) - 1]/6$$

$$S9 = [(Question\ 9) - 1]/4$$

$$\text{Symptom Frequency Score} = 100 * (\text{mean of } S3, S5, S7 \text{ and } S9)$$

### 4. Symptom Burden

- Code responses to each of Questions 4, 6 and 8 as follows:

Extremely bothersome = 1

Quite a bit bothersome = 2

Moderately bothersome = 3

Slightly bothersome = 4

Not at all bothersome = 5

I've had no swelling/fatigue/shortness of breath = 5

- If at least one of Questions 4, 6 and 8 is not missing, then compute

$$\text{Symptom Burden Score} = 100 * [(\text{mean of Questions 4, 6 and 8 actually answered}) - 1]/4$$

### 5. Total Symptom Score

= mean of the following available summary scores:

Symptom Frequency Score

Symptom Burden Score

## 6. Self-Efficacy

- Code responses to Questions 10 and 11 as follows:

### Question 10

Not at all sure = 1  
 Not very sure = 2  
 Somewhat sure = 3  
 Mostly sure = 4  
 Completely sure = 5

### Question 11

Do not understand at all = 1  
 Do not understand very well = 2  
 Somewhat understand = 3  
 Mostly understand = 4  
 Completely understand = 5

- If at least one of Questions 10 and 11 is not missing, then compute

$$\text{Self-Efficacy Score} = 100 * [(\text{mean of Questions 10 and 11 actually answered}) - 1] / 4$$

## 7. Quality of Life

- Code responses to Questions 12, 13 and 14 as follows:

### Question 12

It has extremely limited my enjoyment of life = 1  
 It has limited my enjoyment of life quite a bit = 2  
 It has moderately limited my enjoyment of life = 3  
 It has slightly limited my enjoyment of life = 4  
 It has not limited my enjoyment of life at all = 5

### Question 13

Not at all satisfied = 1  
 Mostly dissatisfied = 2  
 Somewhat satisfied = 3  
 Mostly satisfied = 4  
 Completely satisfied = 5

### Question 14

I felt that way all of the time = 1  
 I felt that way most of the time = 2  
 I occasionally felt that way = 3  
 I rarely felt that way = 4  
 I never felt that way = 5

## 7. Quality of Life (cont.)

- If at least one of Questions 12, 13 and 14 is not missing, then compute

$$\text{Quality of Life Score} = 100 * [(\text{mean of Questions 12, 13 and 14 actually answered}) - 1] / 4$$

## 8. Social Limitation

- Code responses to each of Questions 15a-d as follows:

Severely limited = 1

Limited quite a bit = 2

Moderately limited = 3

Slightly limited = 4

Did not limit at all = 5

Does not apply or did not do for other reasons = *<missing value>*

- If at least two of Questions 15a-d are not missing, then compute

$$\text{Social Limitation Score} = 100 * [(\text{mean of Questions 15a-d actually answered}) - 1] / 4$$

## 9. Overall Summary Score

= mean of the following available summary scores:

Physical Limitation Score

Total Symptom Score

Quality of Life Score

Social Limitation Score

## 10. Clinical Summary Score

= mean of the following available summary scores:

Physical Limitation Score

Total Symptom Score

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Note: references to “**means of questions actually answered**” imply the following.

- If there are  $n$  questions in a scale, and the subject must answer  $m$  to score the scale, but the subject answers only  $n-i$ , where  $n-i \geq m$ , calculate the **mean of those questions** as  
 $(\text{sum of the responses to those } n-i \text{ questions}) / (n-i)$   
**not**  
 $(\text{sum of the responses to those } n-i \text{ questions}) / n$

If doing these calculations seems like too much trouble, consider using one of our tools – available at [www.cvoutcomes.org](http://www.cvoutcomes.org):

- SAS or SPSS code
- Excel spreadsheets
- Web data services

## The Patient Health Questionnaire-2 (PHQ-2)

**Instructions:** Print out the short form below and ask patients to complete it while sitting in the waiting or exam room.

**Use:** The purpose of the PHQ-2 is not to establish a final diagnosis or to monitor depression severity, but rather to screen for depression as a “first-step” approach.

**Scoring:** A PHQ-2 total score (sum of responses from both questions) ranges from 0 to 6; patients with scores of 3 or more should be further evaluated.

Patient Name: _____ Date of Visit: _____				
Over the past 2 weeks, how often have you been bothered by any of the following problems?	Not at all	Several days	More than one-half of 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

Kroenke K, Spitzer RL, Williams JB. The Patient Health Questionnaire-2: validity of a two-item depression screener. *Med Care*. 2003;41:1284-1292. ©2007CQAIMH. All rights reserved. Used with permission.

### Adherence measures used in

Voils, C. I., King, H. A., Neelon, B., Hoyle, R. H., Reeve, B. B., Maciejewski, M. L., & Yancy Jr., W. S. (2014). Characterizing weekly self-reported antihypertensive medication nonadherence across repeated occasions. *Patient Preference and Adherence*, 8, 643-650. PMID: 24855340.

### Part 1: Extent of Nonadherence

In order for a water pill to work best, people should take it according to the doctor's instructions. For one reason or another, people can't or don't always take all of their pills as prescribed. We want to know how often you have missed your [torsemide (Demadex) / furosemide (Lasix) / bumetanide] medication over the past 7 days.

[Interviewer to fill in the italicized text throughout the instrument based on what the patient reported as their current prescribed loop diuretic]

Over the past 7 days...	1 Never	2 Rarely	3 Sometimes	4 Often	5 Always
1. I took all doses of my [torsemide / furosemide / bumetanide] medication. (reverse-scored)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. I missed or skipped at least one dose of my [torsemide / furosemide / bumetanide] medication.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. I was not able to take all of my [torsemide / furosemide / bumetanide] medication.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Scoring instructions: A total score reflecting non-adherence is calculated by averaging responses to items 1 (reverse-scored), 2, and 3. Score only if at least 2 of the 3 items are non-missing.

Dichotomized scoring:

Adherence = perfect score on all items, i.e., Q1=5, Q2=1, Q3=1;

Non-adherence = any response other than perfect adherence, i.e., Q1=1-4, Q2=2-5, Q3=2-5

## Part 2: Reasons for Nonadherence

Situations come up that make it difficult for people to take their **water pill** as prescribed by their doctors. Below is a list of those situations. We want to know how much these situations have interfered with your ability to take your medication. Only one of these situations may apply to you, or many may apply to you.

Over the past 7 days, how much did each situation interfere with your ability to take your **[torsemide / furosemide / bumetanide]** medication?

	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
1. I was busy	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
2. I forgot	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
3. The medication caused some side effects	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
4. I worried about taking <b>it</b> for the rest of my life	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
5. <b>It</b> costs a lot of money	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
6. I came home late	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
7. I did not have any symptoms of <b>extra fluid</b>	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
8. I was with friends or family members	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
9. I was in a public place	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
10. I was afraid of becoming dependent on <b>it</b>	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
11. I was afraid <b>it</b> may affect my sexual performance	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
12. The time to take <b>it</b> was between my meals	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
13. I felt I did not need <b>it</b>	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
14. I was travelling	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
15. I was supposed to take <b>it</b> too many times a day	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>
16. I had other medications to take	Not at all <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	Very much <input type="radio"/>

17. I felt well	Not at all				Very much
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. <b>It makes</b> me need to urinate too often	Not at all				Very much
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. I ran out of medication	Not at all				Very much
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. I was afraid the medication would interact with other medication I take.	Not at all				Very much
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. My blood pressure was too low.	Not at all				Very much
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. I was feeling too ill to take it.	Not at all				Very much
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. I was going on a long car/bus/plane.	Not at all				Very much
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. I didn't want to.	Not at all				Very much
	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Scoring instructions: These items can be used individually as descriptions for why a participant was nonadherent; no total score should be computed.

Patient number \_\_\_\_\_ - \_\_\_\_\_ Patient initials \_\_\_\_\_

Intervals:  interval  30 day  6 month  12 month  18 month  24 month  30 month

**FINAL QUESTIONNAIRE STATUS:** qstatus

Date of Qx: \_\_/\_\_/\_\_\_\_ qxdt  
m m d d y y y y

- 1 Complete
- 2 Incomplete →→→→→→→→
- 3 Not Done →→→→→→→→

**SOURCE OF INFORMATION:** infosrc

- 1 Patient
- 2 Proxy
- 3 Medical record
- 4 Caregiver: If checked, relationship to patient: \_\_\_\_\_
- 5 12 Month Medical Record Check
- 6 Obit

If proxy, specify relationship: proxysel

- 1 Spouse
- 2 Daughter/Son
- 3 Son-in-law/Daughter-in-law
- 4 Grandchild
- 5 Parent of patient
- 6 Brother/sister
- 7 Nephew/niece
- 8 Cousin
- 9 Other Relative
- 10 Friend
- 11 Boarder/Renter
- 12 Health Aide
- 13 Other Unrelated
- 14 Staff member at institution

**HOW DATA WAS COLLECTED:** admntype

- 1 Phone
- 2 Internet Search
- 3 Other admntypeoth \_\_\_\_\_

**RESIDENCE:** residenc

(Of pt. at time summary completed)

- 1 Community/ Home
- 2 Acute Care (in-pt. hospital)
- 3 Nursing Home/Hospice
- 4 Rehab Institution

**INTERVIEWER:** interviewer \_\_\_\_\_

**REASON FOR INCOMPLETE OR NOT DONE:** misreas

(DROP DOWN)

- 1 Patient died: Date of Death \_\_/\_\_/\_\_\_\_ dthdt  
m m d d y y y y

**(Please complete End of Study (EOS) form)**

- Was patient hospitalized at time of death? dthosp
  - 1 Yes
  - 2 No

- 2 Withdrawn **(Please complete EOS form)**
- 3 Modified Participation
- 4 Patient too ill
- 5 Patient deaf
- 6 Patient unreliable
- 7 Language barrier
- 8 Situation not conducive for phone call
- 9 Patient refused
- 10 Patient incarcerated
- 11 Unable to locate/contact patient (UTL/UTC)
  - No valid contacts (patient or alternates)
  - Multiple attempts to valid contacts
- Date Last Contact Alive: \_\_/\_\_/\_\_\_\_ lastcondtm  
m m d d y y y y lastcondtd lastcondty
- 12 Other: Specify: missoth \_\_\_\_\_

**LANGUAGE:** crflang

- 1 English
- 2 Spanish
- 99 Other crflangoth \_\_\_\_\_

**COMMENTS:** comments

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Follow-Up Case Report Form

DCRI-CONNECT-HF

**HOSPITALIZATIONS (This will be a repeating form for as many hospitalizations the patient reports) {30 days, 6 months, and 12 months only}**

**CRFFUP**

Since your hospital discharge/last interview [insert date], have you been back to the hospital for any reason? *rehosp*

- Yes <sup>1</sup>
- No [If no, skip to the medication tab] <sup>2</sup>
- Confirmed Missing <sup>-5</sup>
- Don't Know <sup>-8</sup>
- Refused <sup>-9</sup>

If yes, please describe when and where you were hospitalized, starting with the earliest visit.

**CRFFUPHOSP**

Date of Hospital Visit:

\_\_\_\_/\_\_\_\_/\_\_\_\_  
MM DD YYYY

*hcsadmtm*  
*hcsadmtd*  
*hcsadmdty*

Hospital Name: *hospname*

Address: *hospaddr*

City, State: *hospcity*  
*hospstat*

Admission Type (check all that apply):

For each admission type, these are the answer choices:

- Yes <sup>1</sup>
- No <sup>2</sup>
- Confirmed Missing <sup>-5</sup>
- Refused <sup>-8</sup>

- Inpatient Admission *adstat\_admit*
- ER Visit Only/Observational Stay *adstat\_eronly*
- Outpatient Procedure *adstat\_outpat*
- Other *adstat\_oth* *adstat\_othtxt*
- Can't Remember *adstat\_notremem*

Was this an urgent or unplanned visit?

*urgentunpl*

- Yes <sup>1</sup>
- No <sup>2</sup>
- Confirmed Missing <sup>-5</sup>
- Don't Know <sup>-8</sup>
- Refused <sup>-9</sup>

Main Reason for Hospitalization

For each reason, these are the answer choices: *hreas\_main*

- Heart Failure <sup>1</sup>
- Arrhythmia (abnormal heart rhythm) <sup>2</sup>
- Acute Myocardial Infarction (heart attack) <sup>3</sup>

**CRFFUPHOSP dataset NOT provided. The data from this dataset is provided in the analysis dataset HOSPADS (one record per hosp). HOSPADS used in the final analyses.**

Site ID: \_\_\_\_\_ Patient ID: \_\_\_\_\_

**Follow-Up Case Report Form** CRFFUPHOSP

- Procedures such as heart catheterization or Pacemaker/ICD <sup>4</sup>
- Other Cardiovascular Reason (other reason related to your heart or blood vessels) Specify: \_\_\_\_\_ <sup>5</sup>
- Other non-cardiovascular Reason (reason not related to your heart or blood vessels) Specify: \_\_\_\_\_ <sup>6</sup>
- Unknown <sup>7</sup>
- Can't Remember <sup>8</sup>

Follow-Up Case Report Form

DCRI-CONNECT-HF CRFFUPHOSP

**REVIEW OF PRIOR MEDICATIONS [Repeating form for each medication] { Collect at all intervals}**

Medication <small>dmed=medication name dmedft=free text med, 9999 (other)</small>	AKA	Still Prescribed...  <small>dmedstat</small>	If still Prescribed... <b>[Collect only on specified medications]</b>		If Not Prescribed... <b>[Collect only for loop diuretic medications]</b>	
			Dose <small>dmeddose</small>	Frequency <small>dmedfreq</small>	Why was this medication not prescribed? (check all that apply) <b>For each reason below, these will be the answer choices:</b>	
		<input type="radio"/> Yes <sup>1</sup> <input type="radio"/> No <sup>2</sup> <input type="radio"/> Confirmed <input type="radio"/> Missing <sup>-5</sup> <input type="radio"/> Refused <sup>-9</sup>	<small>dmeddosetxt</small> <input type="radio"/> Confirmed <input type="radio"/> Missing <sup>-5</sup> <input type="radio"/> Refused <sup>-9</sup>	<input type="radio"/> Daily <sup>1</sup> <input type="radio"/> 2x Day <sup>2</sup> <input type="radio"/> 3x Day <sup>3</sup> <input type="radio"/> 4x Day <sup>4</sup> <input type="radio"/> Every other Day <sup>5</sup> <input type="radio"/> Once a Week <sup>6</sup> <input type="radio"/> Other <sup>dmedfreqtxt</sup> <input type="radio"/> Confirmed <sup>-5</sup> <input type="radio"/> Missing <input type="radio"/> Refused <sup>-9</sup>  <input type="checkbox"/> As Needed <small>dmedasneeded</small>	<input type="radio"/> Yes <sup>1</sup> <input type="radio"/> No <sup>2</sup> <input type="radio"/> Confirmed <input type="radio"/> Missing <sup>-5</sup> <input type="radio"/> Refused <sup>-9</sup>	
					<p>What reason were you not prescribed this medication? (select all that apply)</p> <input type="checkbox"/> Doctor told me I no longer needed to be on it or should take a different medicine <small>dmedstop_reas1</small> <input type="checkbox"/> I (or my doctor) felt it was hurting my kidneys <small>dmedstop_reas2</small> <input type="checkbox"/> I (or my doctor) felt it was causing me to feel dizzy/lightheaded <small>dmedstop_reas3</small> <input type="checkbox"/> I (or my doctor) felt it was causing my blood pressure to be low <small>dmedstop_reas4</small> <input type="checkbox"/> I (or my doctor) felt it is causing me other side effects/symptoms not included above <small>dmedstop_reas5</small> <input type="checkbox"/> It was too expensive <small>dmedstop_reas7</small> <input type="checkbox"/> Other <small>dmedstop_oth</small>	

Follow-Up Case Report Form

CRFFUPMED

**NEW MEDICATIONS [Repeating form for each medication] { Collect at all intervals}**

Medication Name	AKA	Medication (only collect for specified medications)	
		Dose <small>dmeddose</small>	Frequency <small>dmedfreq</small>
<small>dmed=medication name</small> <small>dmed = 9999 (other) then dmedftis filled in</small>		<hr/> <input type="radio"/> Confirmed Missing <small>-5</small> <input type="radio"/> Refused <small>-9</small>	<input type="radio"/> Daily <small>1</small> <input type="radio"/> 2x Day <small>2</small> <input type="radio"/> 3x Day <small>2</small> <input type="radio"/> 4x Day <small>4</small> <input type="radio"/> Every other Day <small>5</small> <input type="radio"/> Once a Week <small>6</small> <input type="radio"/> Other <small>7</small> <small>dmedfreqtx</small> <input type="radio"/> Confirmed Missing <small>-5</small> <input type="radio"/> Refused <small>.9</small>  <input type="checkbox"/> As Needed <small>dmedasneeded</small>
		<hr/>	<input type="radio"/> Daily <input type="radio"/> 2x Day <input type="radio"/> 3x Day <input type="radio"/> 4x Day <input type="radio"/> Every other Day <input type="radio"/> Once a Week <input type="radio"/> Other _____ <input type="checkbox"/> As Needed
		<hr/>	<input type="radio"/> Daily <input type="radio"/> 2x Day <input type="radio"/> 3x Day <input type="radio"/> 4x Day <input type="radio"/> Every other Day <input type="radio"/> Once a Week <input type="radio"/> Other _____ <input type="checkbox"/> As Needed

Follow-Up Case Report Form **CRFFUP**

**RANDOMIZED LOOP DIURETIC: { Collect at all intervals }**

<i>"It looks like you are not prescribed &lt;randomized loop diuretic&gt;. Is this correct?"</i>	If Yes (Not Prescribed)....	If No (Still Prescribed)....
confirmloop	<p>Why was this medication not prescribed? (check all that apply) For each reason below, these will be the answer choices:</p> <ul style="list-style-type: none"> <li><input type="radio"/> Yes 1</li> <li><input type="radio"/> No 2</li> <li><input type="radio"/> Confirmed Missing -5</li> <li><input type="radio"/> Refused -9</li> <li><input type="radio"/> Don't know -8</li> </ul>	<p>Interviewer should be instructed to add the randomized loop diuretic to the medication list in the model database on previous tab.</p>
<ul style="list-style-type: none"> <li><input type="radio"/> Yes 1</li> <li><input type="radio"/> No 2</li> <li><input type="radio"/> Confirmed Missing -5</li> <li><input type="radio"/> Refused -9</li> </ul>	<p>What reason were you not prescribed this medication? (select all that apply)</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Doctor told me I no longer needed to be on it or should take a different medicine nolooprsn1</li> <li><input type="checkbox"/> I (or my doctor) felt it was hurting my kidneys nolooprsn2</li> <li><input type="checkbox"/> I (or my doctor) felt it was causing me to feel dizzy/lightheaded nolooprsn3</li> <li><input type="checkbox"/> I (or my doctor) felt it was causing my blood pressure to be low nolooprsn4</li> <li><input type="checkbox"/> I (or my doctor) felt it is causing me other side effects/symptoms not included above nolooprsn5</li> <li><input type="checkbox"/> It was too expensive nolooprsn6</li> <li><input type="checkbox"/> Other nolooprsn7</li> </ul>	

**Notes: This question should be asked at each interval where the randomized loop diuretic is not listed as "Still Prescribed" on the medication list.**

**The question should NOT appear if randomized loop is on the medication list, but patient reports not prescribed in the same interval and answer the reasons why it is no longer prescribed.**

Follow-Up Case Report Form **CRFFUP**

**VOILS {Only asked for patients still taking a loop diuretic} { Collect at all intervals}**

In order for a water pill to work best, people should take it according to the doctor's instructions. For one reason or another, people can't or don't always take all of their pills as prescribed. We want to know how often you have missed your {insert prescribed loop diuretic (torsemide/Demadex, furosemide/Lasix, bumetanide/Bumex, ethacrynic acid/Edecrin) medication over the last 7 days. **[Besides the answer choices below, there will also be Confirmed Missing (=5), Don't Know (=8), Refused (=9)]**

1. Over the past 7 days...	Never <sup>1</sup>	Rarely <sup>2</sup>	Sometimes <sup>3</sup>	Often <sup>4</sup>	Always <sup>5</sup>
a. I took all doses of my {insert prescribed loop diuretic} medication <small>voilsall</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. I missed or skipped at least one dose of my {insert prescribed loop diuretic} medication <small>voilsskip</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. I was not able to take all of my {insert prescribed loop diuretic} medication <small>voilsnotabl</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Situations come up that make it difficult for people to take their water pill as prescribed by their doctors. Below is a list of these situations. We want to know how much of these situations have interfered with your ability to take your medication. Only one of these situations may apply to you or many may apply to you.

2. Over the past 7 days, how much did each situation interfere with your ability to take your {insert prescribed loop diuretic} medication? **[Besides the answer choices below, there will also be Confirmed Missing (=5), Don't Know (=8), Refused(=9)]**

	1 Not at all	2	3	4	5 Very much
a. I was busy <small>voilsbusy</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. I forgot <small>voilsforgot</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. The medication caused some side effects <small>voilssideeff</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. I worried about taking it for the rest of my life <small>voilsrestlife</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. It costs a lot of money <small>voilsmoney</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. I came home late <small>voilshomlat</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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g. I did not have any symptoms of extra fluid	voilsnosymp	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
h. I was with friends or family members	voilsfrndsfam	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
i. I was in a public place	voilspublic	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
j. I was afraid of becoming dependent on it	voilsdepend	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
k. I was afraid it may affect my sexual performance	voilsexperf	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
l. The time to take it was between my meals	voilsbtwnmeal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
m. I felt I did not need it	voilsnoneed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
n. I was traveling	voilstravel	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
o. I was supposed to take it too many times a day	voilstoomany	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
p. I had other medications to take	voilsothermed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
q. I felt well	voilsfeltwell	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
r. It makes me need to urinate too often	voilsurinate	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
s. I ran out of medication	voilsranout	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
t. I was afraid the medication would interact with other medication I take	voilsothmed	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
u. My blood pressure was too low	voilslobp	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
v. I was feeling too ill to take it	voilsill	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
w. I was going on a long car/bus/plane	voilsbusplane	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
x. I didn't want to	voilsdidntwant	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Follow-Up Case Report Form **CRFFUP**

**PHQ-2 {30 days, 6 months, and 12 months only}**

3. Over the last 2 weeks, how often have you been bothered by any of the following problems?

*(Besides the answer choices below, there will also be Confirmed Missing, Don't Know, Refused)*

	Not at all <sup>1</sup>	Several Days <sup>2</sup>	More than half the days <sup>3</sup>	Nearly every day <sup>4</sup>
a. Little Interest or pleasure in doing things <small>phqdep</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Feeling down, depressed or hopeless <small>phqpoint</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

-5 Confirmed Missing

-8 Don't Know

-9 Refused

Follow-Up Case Report Form **CRFFUP**

**KCCQ {30 days, 6 months, and 12 months only}**


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 give the answer that best applies to you. **[Besides the answer choices below, there will also be Confirmed Missing (= -5), Don't Know (= -8), Refused (= -9)]**

4. **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.

Activity	Extremely Limited 1	Quite a bit Limited 2	Moderately Limited 3	Slightly Limited 4	Not at all Limited 5	Limited for other reasons or did not do the activity 6
a. Dressing Yourself <small>kcdress</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Showering/Bathing <small>kcshowr</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Walking 1 block on level ground <small>kcwalk</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Doing yard work, housework, or carrying groceries <small>kchouswk</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
e. Climbing a flight of stairs without stopping <small>kcstrs</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
f. Hurrying or jogging (as if to catch a bus) <small>kchuryng</small>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. <u>Compared with 2 weeks ago</u> , have your symptoms of heart failure (shortness of breath, fatigue or ankle swelling) changed? My symptoms of heart failure have become... <small>kchfsymp</small>	<input type="radio"/> Much worse 1 <input type="radio"/> Slightly worse 2 <input type="radio"/> Not changed 3 <input type="radio"/> Slightly better 4 <input type="radio"/> Much better 5 <input type="radio"/> I've had no symptoms over the last 2 weeks 6 <div style="text-align: right; color: red;">                     -5 Confirmed Missing                      -8 Don't Know                      -9 Refused                 </div>					
6. Over the <u>past 2 weeks</u> , how many times did you have <b>swelling</b> in your feet, ankles, or legs when you woke up in the morning? <small>kcswltn</small>	<input type="radio"/> Every morning 1 <input type="radio"/> 3 or more times a week but, not every day 2 <input type="radio"/> 1-2 times a week 3 <input type="radio"/> Less than once a week 4 <input type="radio"/> Never over the past 2 weeks 5 <div style="text-align: right; color: red;">                     -5 Confirmed Missing                      -8 Don't Know                      -9 Refused                 </div>					

-5 Confirmed Missing  
-8 Don't Know  
-9 Refused

**Follow-Up Case Report Form CRFFUP**

<p>7. Over the <u>past 2 weeks</u>, how much <b>swelling</b> in your feet, ankles, or legs bothered you? It has been... <span style="color: red;">kcswlamt</span></p>	<p> <input type="radio"/> <b>Extremely</b> bothersome 1  <input type="radio"/> <b>Quite a bit</b> bothersome 2 <span style="color: red;">-5 Confirmed Missing</span>  <input type="radio"/> <b>Moderately</b> bothersome 3 <span style="color: red;">-8 Don't Know</span>  <input type="radio"/> <b>Slightly</b> bothersome 4 <span style="color: red;">-9 Refused</span>  <input type="radio"/> <b>Not at all</b> bothersome 5  <input type="radio"/> I've had <b>no swelling</b> 6         </p>
<p>8. Over the <u>past 2 weeks</u>, on average, how many times has <b>fatigue</b> limited your ability to do what you want? <span style="color: red;">kcftgn</span></p>	<p> <input type="radio"/> All of the time 1 <span style="color: red;">-5 Confirmed Missing</span>  <input type="radio"/> Several times a day 2 <span style="color: red;">-8 Don't Know</span>  <input checked="" type="radio"/> At least once a day 3 <span style="color: red;">-9 Refused</span>   <input type="radio"/> 3 or more times a week but not every day 4  <input type="radio"/> 1-2 times a week 5  <input type="radio"/> Less than once a week 6  <input type="radio"/> Never over the past 2 weeks 7         </p>
<p>9. Over the <u>past 2 weeks</u>, how much has your <b>fatigue</b> bothered you? It has been... <span style="color: red;">kcftgamt</span></p>	<p> <input type="radio"/> <b>Extremely</b> bothersome 1  <input type="radio"/> <b>Quite a bit</b> bothersome 2  <input type="radio"/> <b>Moderately</b> bothersome 3 <span style="color: red;">-5 Confirmed Missing</span>  <input type="radio"/> <b>Slightly</b> bothersome 4 <span style="color: red;">-8 Don't Know</span>  <input type="radio"/> <b>Not at all</b> bothersome 5 <span style="color: red;">-9 Refused</span>  <input type="radio"/> I've had <b>no fatigue</b> 6         </p>
<p>10. Over the <u>past 2 weeks</u>, on average, how many times has <b>shortness of breath</b> limited your ability to do what you wanted? <span style="color: red;">kcsbn</span></p>	<p> <input type="radio"/> All of the time 1 <span style="color: red;">-5 Confirmed Missing</span>  <input type="radio"/> Several times a day 2 <span style="color: red;">-8 Don't Know</span>  <input type="radio"/> At least once a day 3 <span style="color: red;">-9 Refused</span>  <input type="radio"/> 3 or more times a week but not every day 4  <input type="radio"/> 1-2 times a week 5  <input type="radio"/> Less than once a week 6  <input type="radio"/> Never over the past 2 weeks 7         </p>
<p>11. Over the <u>past 2 weeks</u>, how much has your <b>shortness of breath</b> bothered you? It has been... <span style="color: red;">kcsbant</span></p>	<p> <input type="radio"/> <b>Extremely</b> bothersome 1  <input type="radio"/> <b>Quite a bit</b> bothersome 2 <span style="color: red;">-5 Confirmed Missing</span>  <input type="radio"/> <b>Moderately</b> bothersome 3 <span style="color: red;">-8 Don't Know</span>  <input type="radio"/> <b>Slightly</b> bothersome 4 <span style="color: red;">-9 Refused</span>  <input type="radio"/> <b>Not at all</b> bothersome 5  <input type="radio"/> I've had <b>no shortness of breath</b> 6         </p>

Follow-Up Case Report Form **CRFFUP**

<p>12. Over the <u>past 2 weeks</u>, 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 <b>shortness of breath</b>? <span style="color: red;">kcsleep</span></p>	<p> <input type="radio"/> Every night <b>1</b>  <input type="radio"/> 3 or more times a week, but not every day <b>2</b>  <input type="radio"/> 1-2 times a week <b>3</b>  <input type="radio"/> Less than once a week <b>4</b>  <input type="radio"/> Never over the past 2 weeks <b>5</b> </p> <p style="text-align: right; color: red;">         -5 Confirmed Missing          -8 Don't Know          -9 Refused       </p>
<p>13. <b>Heart failure</b> symptoms can worsen for a number of reasons. How sure are you that you know what to do, or whom to call, if your <b>heart failure</b> gets worse? <span style="color: red;">kchfworsen</span></p>	<p> <input type="radio"/> <b>Not at all</b> sure <b>1</b>  <input type="radio"/> <b>Not very</b> sure <b>2</b>  <input type="radio"/> <b>Somewhat</b> sure <b>3</b>  <input type="radio"/> <b>Mostly</b> sure <b>4</b>  <input type="radio"/> <b>Completely</b> sure <b>5</b> </p> <p style="text-align: right; color: red;">         -5 Confirmed Missing          -8 Don't Know          -9 Refused       </p>
<p>14. 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.) <span style="color: red;">kcundsymp</span></p>	<p> <input type="radio"/> Do not understand at all <b>1</b>  <input type="radio"/> Do not understand very well <b>2</b>  <input type="radio"/> <b>Somewhat</b> understand <b>3</b>  <input type="radio"/> <b>Mostly</b> understand <b>4</b>  <input type="radio"/> <b>Completely</b> understand <b>5</b> </p> <p style="text-align: right; color: red;">         -5 Confirmed Missing          -8 Don't Know          -9 Refused       </p>
<p>15. Over the <u>past 2 weeks</u>, how much has your <b>heart failure</b> limited your enjoyment of life? <span style="color: red;">kcenjoy</span></p>	<p> <input type="radio"/> It has <b>extremely</b> limited my enjoyment of life <b>1</b>  <input type="radio"/> It has limited my enjoyment of life <b>quite a bit</b> <b>2</b>  <input type="radio"/> It has <b>moderately</b> limited my enjoyment of life <b>3</b>  <input type="radio"/> It has <b>slightly</b> limited my enjoyment of life <b>4</b>  <input type="radio"/> It has <b>not limited</b> my enjoyment of life <b>5</b> </p> <p style="text-align: right; color: red;">         -5 Confirmed Missing          -8 Don't Know          -9 Refused       </p>
<p>16. 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? <span style="color: red;">kcsatist</span></p>	<p> <input type="radio"/> <b>Not at all</b> satisfied <b>1</b>  <input type="radio"/> <b>Mostly</b> dissatisfied <b>2</b>  <input type="radio"/> <b>Somewhat</b> satisfied <b>3</b>  <input type="radio"/> <b>Mostly</b> satisfied <b>4</b>  <input type="radio"/> <b>Completely</b> satisfied <b>5</b> </p> <p style="text-align: right; color: red;">         -5 Confirmed Missing          -8 Don't Know          -9 Refused       </p>

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<p>17. Over the <u>last 2 weeks</u>, how often have you felt discouraged or down in the dumps because of your heart failure? <i>kcdumps</i></p>		<p> <input type="radio"/> I felt that way <b>all of the time</b> 1      -5 Confirmed Missing  <input type="radio"/> I felt that way <b>most of the time</b> 2      -8 Don't Know  <input type="radio"/> I <b>occasionally</b> felt that way 3      -9 Refused  <input type="radio"/> I <b>rarely</b> felt that way 4  <input type="radio"/> I <b>never</b> felt that way 5         </p>				
<p>18. How much does your <b>heart failure</b> affect your lifestyle? Please indicate how your <b>heart failure</b> may have limited your participation in the following activities over the past 2 weeks?</p>						
Activity	Severely Limited 1	Limited quite a bit 2	Moderately Limited 3	Slightly Limited 4	Did not Limit at all 5	Does not apply or did not do for other reasons 6
a. Hobbies, recreational activities <i>kchobby</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Working or doing household chores <i>kcchores</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Visiting family or friends out of your home <i>kcvisits</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Intimate relationships with loved ones <i>kcrelat</i>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

-5 Confirmed Missing  
-8 Don't Know  
-9 Refused

**Discharge medications summary page (DISCHARG dataset):**

dischargkey (used for merging) datavrsn (=1) interval (=1 Discharge Medications) formname (\$64 = 'frmDISCHARG\_Edit')

Date received **qxdt** : Calendar pick

Final Questionnaire Status **qstatus** : 1- Complete  
2- Incomplete  
3- Not Done

Reason Incomplete/Not Done **missreas** : 1- Patient Died  
2-Withdrawn  
3- No loop diuretic  
4-Never sent by the site  
5-Other **missoth** (\$150)

**Discharge Medications** Study No: 103-015 Form Interval: 1 Discharge Medications

Summary Page 2 Comments

**Discharge Medication Summary**

Study No: 103-015

Date Received: 04/29/2019

Final Questionnaire Status: 3] Not Done Reason Incomplete/Not Done: 4] Never sent by the site

If other, specify:

Open Scanned File

Entered: 03/30/2019 7:00:19 by: sp\_LoadDisc Modified: 04/25/2019 2:00:00 PM by: HARR0059 Validated

ADD EDIT DEL E2T

**Discharge medications Page 2 (DISCHARGMED dataset):**

dischargkey & dischargmedkey (used for merging) and formname (\$64 = 'frmDISCHARG\_Edit')

Medication dmed - *MEDICATIONLIST* dataset contains list of medications

-Other Medication dmedft (\$100)

Dose dmeddose (\$50) - *MEDICATION\_DOSES* dataset contains list of medication doses

-Other Dose dmeddosetxt

Frequency: dmedfreq

-Other Frequency: dmedfreqtxt (\$100)

vlu_dismed_dmedfreq	
choice	choicetext
1	1] Daily
2	2] 2x Day
3	3] 3x Dy
4	4] 4x Day
5	5] Every Other Day
6	6] Once a Week
7	7] Other
-5	-5] Confirmed Missing
-8	-8] Don't Know
-9	-9] Refused

As needed: dmedasneeded

vlu_dismed_dmedasneeded	
choice	choicetext
1	1] Yes
2	2] No
-5	-5] Confirmed Missing
-8	-8 Don't Know
-9	-9 Refused

# Discharge Medications

Study No: 103-015

Form Interval: -1 Discharge Medications

Summary Page 2 Comments

## A. Current Medications

Medication:

AKA:

Medication:

AKA:

Dose:

Other Dose:

Frequency:

Other Freq:

As Needed:

Next -->

Entered: 03/30/2019 7:00:19 by: sp\_LoadDisc Modified: 04/29/2019 2:00:08 PM by: HARRI069

Validated

ADD

EDIT

DEL

EXIT

# TRANSFORM End-of-Study Form PATLOG

Reference  
Variable

Dataset Name

I. Patient status (please select 1 of the 3 choices below) **ptstat**

1. Active Follow-up
2. Withdrawn
3. Deceased

As of Date: \_\_/\_\_/\_\_\_\_

**ptstatdt**

II. Patient Sub-Status **ptsubstat**

1. Full (Default)
2. 12 month phone follow up only
3. Medical Records Only
4. 12 Month Phone Follow-up and Medical Records

As of Date: \_\_/\_\_/\_\_\_\_

**ptsubstat**

A. Active Follow-up

B. Deceased

➤ Date of death: \_\_\_\_/\_\_\_\_/\_\_\_\_ **eos\_dthdt**  
mm dd yyyy

➤ Location of death (choose ONE): **eos\_dthloc**

- In hospital **1**

Name of hospital: **eos\_hospde** \_\_\_\_\_ City/State: \_\_\_\_\_

(Component can be disabled/enabled depending upon study need)

- Non Hospital death **2**

➤ Cause of death: **eos\_dthcause** \_\_\_\_\_

- Cardiovascular **1**
- Non-cardiovascular **2**
- Unknown **3**

Narrative of events or circumstances: **eos\_dthnarr** \_\_\_\_\_

➤ Death Triggered by: **eos\_dthtri**

- Proxy Interview **1**
- Online Search **2**
- Medical Record Search **3**
- Enrolling Site **4**
- National Death Index **5**
- Other **6** \_\_\_\_\_ **eos\_dthtritx**

➤ Death confirmed by: **eos\_dthconf**

- 2<sup>nd</sup> Proxy Interview **1**
- Obit/Grave Markers **2**
- Medical Record **3**
- 
- National Death Index **5**
- Adjudicated by Mortality Review Committee **6**
- Other **7** \_\_\_\_\_ **eos\_dthconftx**
- Unconfirmed Death

C. Withdrawn

➤ Date of withdrawal: \_\_\_\_/\_\_\_\_/\_\_\_\_ **eos\_wddt**  
mm dd yyyy

➤ Type of withdrawal by subject: **eos\_wdtype**

- Verbal **1**
- Written **2**

➤ Withdrawal Location **eos\_wdloc**

- Site **1**
- Follow-up **2**

➤ Did withdrawal occur at baseline? **eos\_wdbase**



**End of Study Variables:**

- Patient Status: Equal to Withdrawn, Deceased, or Active
- As of: This is the date the call-center found out about the change in patient status
- Patient Sub-Status: Equal to Full (Default), 12 month phone follow up only, Medical Records Only, and 12 month phone follow-up and medical records.
- Date of Death: Patients reported date of death
- Location of death: whether the patient died in a hospital or non-hospital
- Hospital Name/City/State: Location of the hospital where patient died
- Cause of Death: Was patients death a result of a cardiovascular issue, non-cardiovascular issue, or unknown if patient did not die in the hospital
- Narrative: If available, comments surrounding patients death if patient did not die in the hospital
- Death Triggered by: How did the resource team come to find out about death: proxy interview, online search, medical record search, enrolling site, NDI, and other.
- Death Confirmed by: Who reported death or who/what confirmed death: 2<sup>nd</sup> proxy interview, obit/grave markers, medical record, enrolling site, NDI, adjudicated by Mortality Review Committee.
- If other: if death was reported by something/someone not listed, then explain
- Date of Withdrawal: date patient withdrew from the study
- Type of Withdrawal: was it a verbal or written withdrawal
- Withdrawal Location: was the withdrawal done with the site or with follow-up
- Did withdrawal occur at baseline: was the withdrawal given prior to discharge from index hospitalization? If yes, then withdraw was at baseline.
- If it occurred during follow-up, what was the reason for withdrawal: Reason the patient gave for withdrawing from the study
- Other reason: If reason for patient withdraw is not listed, include reason in free text
- Post Withdrawal death: Did patient die after they withdrew from the study?
- If yes, Date of death: date of death of patient after withdraw from the study
- If no, Date of Search: date that search was done on patient
- Death Triggered by: How did the resource team learn of the death: proxy interview, online search, enrolling site, NDI, and other.
- Death Confirmed by: Who reported death or who/what confirmed death: proxy interview, obit/grave markers, medical record, enrolling site, NDI, adjudicated by Mortality Review Committee., and other.
- If other: if death was reported by something/someone not listed, then explain
- Overall End of Study Date (i.e date last known alive): If patient withdrew from the study, this date should match the date of withdrawal. If patient is deceased, this date should be 1 day prior to date of death.
- Justification of last known alive date: What was the final determination of the last known alive date.
- Was any contact made with the patient or a proxy during follow-up: Was the call-center able to speak with the patient or proxy during follow-up prior to withdrawal date or before or after death date.
- Comments: any additional comments that are relevant to the end of study
- Date EOS Form Completed: when the EOS was completed
- Completed By: who completed the EOS form

These fields are also in the [PATLOG](#) table:

**HIPAA Revocation Status**

HIPAA Revocation:   As Of:

hipaa\_revoc all missing

**TRANSFORM\_annotated**

Patient ID Number  
 {[record\_id] text}

\_\_\_\_\_

Please review the format of the Patient ID Number above. If it does not meet the XXX-XXX format where the first 3 digits are site number and the 3 digits after the dash is the sequential patient number, please inform the site management team at Transform\_HF@dm.duke.edu so that a correction can be made

Does your site enroll patients at more than one hospital?  
 {[easiteyn] radio}

- {1} Yes  
 {0} No

What is the name of the hospital where this patient was enrolled?  
 {[easitnm2] sql}  
 {Branching logic (show if): [easiteyn] = '1'}

{}

Retired Question: What is the name of the hospital where this patient was enrolled?  
 {[easitenm] text}  
 {Branching logic (show if): [easiteyn] = 1}

\_\_\_\_\_

Date (time) of informed consent:  
 {[icdate] text datetime\_mdy}

\_\_\_\_\_ (mm/dd/yyyy hh:mm )

Patient hospitalized for >= 24 hours or over a change in calendar date?  
 {[eahost] radio}

- {1} Yes  
 {0} No

Patient hospitalized with:  
 {[eahoshf] radio}

- {1} Worsening of chronic heart failure or new diagnosis of heart failure  
 {2} No heart failure

Is there a plan for a daily outpatient oral loop diuretic regimen upon hospital discharge?  
 {[eadaily] radio}

- {1} Yes  
 {0} No

Is there a left ventricular ejection fraction available (by any modality) within 24 months prior to and including the current hospitalization?  
 {[ealvefa] radio}

- {1} Yes  
 {0} No

Left Ventricular Ejection Fraction, %  
 {[ealvef] text float}  
 {Branching logic (show if): [ealvefa] = 1}

\_\_\_\_\_ (Most recent value by any cardiac imaging modality )

Is an NT-proBNP or BNP result available from the current hospitalization?  
 {[earesav] radio}

- {1} Yes  
 {0} No

Which lab result is available?  
 {[earesavw] checkbox}  
 {Branching logic (show if): [earesav] = 1}

- {1} NT-proBNP  
 {2} BNP

---

Highest NT-proBNP value recorded during the current hospitalization, pg/mL

{[eaesntp] text float}

{Branching logic (show if): [eaesavw(1)] = 1}

---

What is the NT-proBNP upper reference limit at local lab, pg/mL?

{[eaesntu] text float}

{Branching logic (show if): [eaesavw(1)] = 1}

---

Highest BNP value recorded during the current hospitalization

{[eaesbnp] text float}

{Branching logic (show if): [eaesavw(2)] = 1}

---

What is the BNP upper reference limit at local lab, pg/mL?

{[eaesbnu] text float}

{Branching logic (show if): [eaesavw(2)] = 1}

---

Is a NT-proBNP or BNP result available from the 24 months prior to the current hospitalization?

{[eaesmn] radio}

{Branching logic (show if): [eaesav] = 0 and

{eaesav} ""}

{1} Yes

{0} No

---

Which lab result is available and most recent?

{[eaesmw] radio}

{Branching logic (show if): [eaesmn] = 1}

---

{1} NT-proBNP

{2} BNP

---

Most recent value, pg/mL

{[eaesmv] text float}

{Branching logic (show if): [eaesmn] = 1}

---

What is the upper reference limit at local lab, pg/mL?

{[eaesul] text float}

{Branching logic (show if): [eaesmn] = 1}

---



---

Does the patient have end-stage renal disease requiring renal replacement therapy?

{[eaerenal] radio}

{1} Yes

{0} No

---

Does the patient have a history of heart transplant or actively listed for heart transplant?

{[ealvad] radio}

{1} Yes

{0} No

---

Does the patient have an implanted LVAD or implant anticipated < 3 months?

{[eaimplv] radio}

{1} Yes

{0} No

---

Is the patient pregnant or nursing?

{[eapreg] radio}

{1} Yes

{0} No

---

---

Does the patient have a malignancy or other non-cardiac condition limiting life expectancy to < 12 months?  
{[eamalig] radio}

- {1} Yes
- {0} No

---

Does the patient have a known hypersensitivity of furosemide, torsemide or related medications?  
{[eahyper] radio}

- {1} Yes
- {0} No

# TRANSFORM\_annotated

---

Date of Birth

{{ddob} text date\_mdy}

\_\_\_\_\_

(mm/dd/yyyy)

---

Sex

{{dsex} radio}

{1} Female

{0} Male

---

Race

{{drace} checkbox}

{1} American Indian or Alaska Native

{2} Chinese

{3} Japanese

{4} Filipino

{5} Other Asian

{6} Black or African American

{7} Native Hawaiian

{8} Pacific Islander

{9} White

{10} Other

(check all that apply)

---

Other race, specify

{{draceo} text}

{Branching logic (show if): [drace(10)] = '1'}

\_\_\_\_\_

---

Ethnicity

{{dethnic} radio}

{1} Hispanic or Latino

{2} Not Hispanic or Latino

**TRANSFORM\_annotated**

Was the KCCQ administered?  
 {[kcc\_adm] radio}  {1} Yes  
 {0} No

Reason  
 {[kcc\_nadm] radio}  
 {Branching logic (show if): [kcc\_adm] = 0 and  
 [kcc\_adm] ""}  
 {1} Patient was too sick  
 {2} Patient refused  
 {3} Questionnaire not available in patient's  
 primary language  
 {4} Unable or forgot to administer  
 {5} Other Reason

**Kansas City Cardiomyopathy Questionnaire**

Was this data collected prior to randomization?  
 {[kcc\_prr] radio}  {1} Yes  
 {0} No  
 {Branching logic (show if): [kcc\_adm] = 1}

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.  
 {Branching logic (show if): [kcc\_adm] = 1}

Dressing yourself  
 {[kcc\_drss] radio}  {1} Extremely Limited  
 {2} Quite a bit Limited  
 {3} Moderately Limited  
 {4} Slightly Limited  
 {5} Not at all Limited  
 {0} Limited for other reasons or did not do the  
 activity  
 {Branching logic (show if): [kcc\_adm] = 1}

Showering/Bathing  
 {[kcc\_shwr] radio}  {1} Extremely Limited  
 {2} Quite a bit Limited  
 {3} Moderately Limited  
 {4} Slightly Limited  
 {5} Not at all Limited  
 {0} Limited for other reasons or did not do the  
 activity  
 {Branching logic (show if): [kcc\_adm] = 1}

Walking 1 block on level ground  
 {[kcc\_walk] radio}  {1} Extremely Limited  
 {2} Quite a bit Limited  
 {3} Moderately Limited  
 {4} Slightly Limited  
 {5} Not at all Limited  
 {0} Limited for other reasons or did not do the  
 activity  
 {Branching logic (show if): [kcc\_adm] = 1}

Doing yardwork, housework, or carrying groceries  
 {[kcc\_yard] radio}  {1} Extremely Limited  
 {2} Quite a bit Limited  
 {3} Moderately Limited  
 {4} Slightly Limited  
 {5} Not at all Limited  
 {0} Limited for other reasons or did not do the  
 activity  
 {Branching logic (show if): [kcc\_adm] = 1}

---

<p>Climbing a flight of stairs without stopping          {[kcc_clmb] radio}          {Branching logic (show if): [kcc_adm] = 1}</p>	<p><input type="radio"/> {1} Extremely Limited  <input type="radio"/> {2} Quite a bit Limited  <input type="radio"/> {3} Moderately Limited  <input type="radio"/> {4} Slightly Limited  <input type="radio"/> {5} Not at all Limited  <input type="radio"/> {0} Limited for other reasons or did not do the activity</p>
---	---

---

<p>Hurrying or jogging (as if to catch a bus)          {[kcc_hrry] radio}          {Branching logic (show if): [kcc_adm] = 1}</p>	<p><input type="radio"/> {1} Extremely Limited  <input type="radio"/> {2} Quite a bit Limited  <input type="radio"/> {3} Moderately Limited  <input type="radio"/> {4} Slightly Limited  <input type="radio"/> {5} Not at all Limited  <input type="radio"/> {0} Limited for other reasons or did not do the activity</p>
---	---

---

<p>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. . .          {[kcc_q2] dropdown}          {Branching logic (show if): [kcc_adm] = 1}</p>	<p><input type="radio"/> {1} Much worse  <input type="radio"/> {2} Slightly worse  <input type="radio"/> {3} Not changed  <input type="radio"/> {4} Slightly better  <input type="radio"/> {5} Much better  <input type="radio"/> {3.1} I've had no symptoms over the last 2 weeks</p>
---	--

---

<p>3. Over the past 2 weeks, how many times did you have swelling in your feet, ankles or legs when you wake up in the morning?          {[kcc_q3] dropdown}          {Branching logic (show if): [kcc_adm] = 1}</p>	<p><input type="radio"/> {1} Every morning  <input type="radio"/> {2} 3 or more times a week, but not every day  <input type="radio"/> {3} 1-2 times a week  <input type="radio"/> {4} Less than once a week  <input type="radio"/> {5} Never over the past 2 weeks</p>
--	---

---

<p>4. Over the past 2 weeks, how much has swelling in your feet, ankles or legs bothered you?          It has been. . .          {[kcc_q4] dropdown}          {Branching logic (show if): [kcc_adm] = 1}</p>	<p><input type="radio"/> {1} Extremely bothersome  <input type="radio"/> {2} Quite a bit bothersome  <input type="radio"/> {3} Moderately bothersome  <input type="radio"/> {4} Slightly bothersome  <input type="radio"/> {5} Not at all bothersome  <input type="radio"/> {5.1} I've had no swelling</p>
--	--

---

<p>5. Over the past 2 weeks, on average, how many times has fatigue limited your ability to do what you want?          {[kcc_q5] dropdown}          {Branching logic (show if): [kcc_adm] = 1}</p>	<p><input type="radio"/> {1} All of the time  <input type="radio"/> {2} Several times per day  <input type="radio"/> {3} At least once a day  <input type="radio"/> {4} 3 or more times per week but not every day  <input type="radio"/> {5} 1-2 times per week  <input type="radio"/> {6} Less than once a week  <input type="radio"/> {7} Never over the past 2 weeks</p>
--	--

---

<p>6. Over the past 2 weeks, how much has your fatigue bothered you?          It has been. . .          {[kcc_q6] dropdown}          {Branching logic (show if): [kcc_adm] = 1}</p>	<p><input type="radio"/> {1} Extremely bothersome  <input type="radio"/> {2} Quite a bit bothersome  <input type="radio"/> {3} Moderately bothersome  <input type="radio"/> {4} Slightly bothersome  <input type="radio"/> {5} Not at all bothersome  <input type="radio"/> {5.1} I've had no fatigue</p>
---	---

---

<p>7. Over the past 2 weeks, on average, how many times has shortness of breath limited your ability to do what you wanted?          {[kcc_q7] dropdown}          {Branching logic (show if): [kcc_adm] = 1}</p>	<p><input type="radio"/> {1} All of the time  <input type="radio"/> {2} Several times per day  <input type="radio"/> {3} At least once a day  <input type="radio"/> {4} 3 or more times per week but not every day  <input type="radio"/> {5} 1-2 times per week  <input type="radio"/> {6} Less than once a week  <input type="radio"/> {7} Never over the past 2 weeks</p>
--	--

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

It has been. . .

{[kcc\_q8] dropdown}

{Branching logic (show if): [kcc\_adm] = 1}

- {1} Extremely bothersome  
 {2} Quite a bit bothersome  
 {3} Moderately bothersome  
 {4} Slightly bothersome  
 {5} Not at all bothersome  
 {5.1} 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?

{[kcc\_q9] dropdown}

{Branching logic (show if): [kcc\_adm] = 1}

- {1} Every night  
 {2} 3 or more times a week, but not every day  
 {3} 1-2 times a week  
 {4} Less than once a week  
 {5} 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?

{[kcc\_q10] dropdown}

{Branching logic (show if): [kcc\_adm] = 1}

- {1} Not at all sure  
 {2} Not very sure  
 {3} Somewhat sure  
 {4} Mostly sure  
 {5} 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.)

{[kcc\_q11] dropdown}

{Branching logic (show if): [kcc\_adm] = 1}

- {1} Do not understand at all  
 {2} Do not understand very well  
 {3} Somewhat understand  
 {4} Mostly understand  
 {5} Completely understand

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

{[kcc\_q12] dropdown}

{Branching logic (show if): [kcc\_adm] = 1}

- {1} It has extremely limited my enjoyment of life  
 {2} It has limited my enjoyment of life quite a bit  
 {3} It has moderately limited my enjoyment of life  
 {4} It has slightly limited my enjoyment of life  
 {5} 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?

{[kcc\_q13] dropdown}

{Branching logic (show if): [kcc\_adm] = 1}

- {1} Not at all satisfied  
 {2} Mostly dissatisfied  
 {3} Somewhat satisfied  
 {4} Mostly satisfied  
 {5} Completely satisfied

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

{[kcc\_q14] dropdown}

{Branching logic (show if): [kcc\_adm] = 1}

- {1} I felt that way all of the time  
 {2} I felt that way most of the time  
 {3} I occasionally felt that way  
 {4} I rarely felt that way  
 {5} 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.

{Branching logic (show if): [kcc\_adm] = 1}

Hobbies, recreational activities

{[kcc\_hbby] radio}

{Branching logic (show if): [kcc\_adm] = 1}

- {1} Severely limited  
 {2} Limited quite a bit  
 {3} Moderately limited  
 {4} Slightly limited  
 {5} Did not limit at all  
 {0} Does not apply or did not do for other reasons

---

Working or doing household chores  
{[kcc\_work] radio}  
{Branching logic (show if): [kcc\_adm] = 1}

- {1} Severely limited
- {2} Limited quite a bit
- {3} Moderately limited
- {4} Slightly limited
- {5} Did not limit at all
- {0} Does not apply or did not do for other reasons

---

Visiting family or friends out of your home  
{[kcc\_fmly] radio}  
{Branching logic (show if): [kcc\_adm] = 1}

- {1} Severely limited
- {2} Limited quite a bit
- {3} Moderately limited
- {4} Slightly limited
- {5} Did not limit at all
- {0} Does not apply or did not do for other reasons

---

Intimate relationships with loved ones  
{[kcc\_relt] radio}  
{Branching logic (show if): [kcc\_adm] = 1}

- {1} Severely limited
- {2} Limited quite a bit
- {3} Moderately limited
- {4} Slightly limited
- {5} Did not limit at all
- {0} Does not apply or did not do for other reasons

**TRANSFORM\_annotated**


---

Was the PHQ-2 administered?  
{[phqadm] radio}  {1} Yes  
 {0} No

---

Was this data collected prior to randomization?  
{[phqdpryn] radio}  {1} Yes  
{Branching logic (show if): [phqadm] = 1}  {0} No

---

Reason  
{[phqreas] radio}  {1} Patient was too sick  
{Branching logic (show if): [phqadm] = 0 and [phqadm]  {2} Patient refused  
""}  {3} Questionnaire not available in patient's  
primary language  
 {4} Unable or forgot to administer  
 {5} Other Reason

---

Over the past 2 weeks, how often have you been bothered by any of the following problems?  
{Branching logic (show if): [phqadm] = '1'}

	{0} Not At All	{1} Several Days	{2} More Than Half the Days	{3} Nearly Every Day
Little interest or pleasure in doing things {[phqq1] radio} {Branching logic (show if): [phqadm] = '1'}	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling down, depressed or hopeless {[phqq2] radio} {Branching logic (show if): [phqadm] = '1'}	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

# TRANSFORM\_annotated

---

What is the planned starting dose if the patient is randomized to:

## Furosemide Dose

Total oral daily dose, mg  
{[dfdose] text float} \_\_\_\_\_

---

Was the Furosemide total oral daily dose collected prior to randomization?  
{[dfdosepr] radio}  
{Branching logic (show if): [dfdose] "" and [dfdose] > 0}

- {1} Yes  
 {0} No

## Torsemide Dose

Total oral daily dose, mg  
{[dtdose] text float} \_\_\_\_\_

---

Was the Torsemide total oral daily dose collected prior to randomization?  
{[dtdospr] radio}  
{Branching logic (show if): [dtdose] "" and [dtdose] > 0}

- {1} Yes  
 {0} No

# TRANSFORM\_annotated

---

Most recent vital sign value closest to, prior to, randomization

---

Systolic blood pressure, mmHg  
{[vsbpsys] text float} \_\_\_\_\_

---

Diastolic blood pressure, mmHg  
{[vsbpdias] text float} \_\_\_\_\_

---

Heart rate, BPM  
{[vshrtrt] text float} \_\_\_\_\_

---

---

Height  
{[vshgtin] text float} \_\_\_\_\_

---

{[vshgtcm] radio}

- {1} Inches
- {2} Centimeters

---

Weight  
{[vswgtlbs] text float} \_\_\_\_\_

---

{[vswgtkgs] radio}

- {1} Pounds
- {2} Kilograms

# TRANSFORM\_annotated

---

Most recent lab value closest to, prior to, randomization

---

Sodium, mEq/L (equivalent to mmol/L)  
{[lbsodium] text float}

---

Potassium, mEq/L (equivalent to mmol/L)  
{[lbpotasm] text float}

---

---

Blood urea nitrogen (BUN)  
{[lbbunmg] text float}

---

{[lbbunmm] radio}

- {1} mg/dL  
 {2} mmol/L
- 

---

Serum Creatinine  
{[lbscmg] text float}

---

{[lbscmicr] radio}

- {1} mg/dL  
 {2} micromoles/L
- 

---

Hemoglobin  
{[lbhemgdl] text float}

---

{[lbhemgl] radio}

- {1} g/dL  
 {2} g/L

**TRANSFORM\_annotated**


---

Is the patient being randomized?  
 {[randyn] radio}  {1} Yes  
 {0} No

---

Reason subject was NOT randomized (check one)  
 {[randnrsn] radio}  
 {Branching logic (show if): [randyn] = 0 and [randyn] = ""}

{1} Patient did not meet one or more of the eligibility criteria  
 {2} Patient decision to withdraw from the study prior to randomization  
 {3} PI decision to withdraw patient from the study prior to randomization  
 {4} Patient was discharged before randomization occurred  
 {5} Patient died prior to randomization

---

The following must be all green in order to meet randomizing criteria:  
 {Branching logic (show if): [randyn] = 1}

---

Patient hospitalized for >= 24 hours or over a change in calendar date: [enrollment\_eligib\_arm\_1][eahost]  
 {Branching logic (show if): [randyn] = 1 and ( [enrollment\_eligib\_arm\_1][eahost] = 0 or [enrollment\_eligib\_arm\_1][eahost] = "" )}

---

Patient hospitalized for >= 24 hours or over a change in calendar date: [enrollment\_eligib\_arm\_1][eahost]  
 {Branching logic (show if): [randyn] = 1 and [enrollment\_eligib\_arm\_1][eahost] = 1}

---

Patient hospitalized with: [enrollment\_eligib\_arm\_1][eahoshf]  
 {Branching logic (show if): [randyn] = 1 and ([enrollment\_eligib\_arm\_1][eahoshf] = 2 or [enrollment\_eligib\_arm\_1][eahoshf] = "" )}

---

Patient hospitalized with: [enrollment\_eligib\_arm\_1][eahoshf]  
 {Branching logic (show if): [randyn] = 1 and [enrollment\_eligib\_arm\_1][eahoshf] = 1}

---

Plan for a daily outpatient oral loop diuretic regimen upon hospital discharge: [enrollment\_eligib\_arm\_1][eadaily]  
 {Branching logic (show if): [randyn] = 1 and ([enrollment\_eligib\_arm\_1][eadaily] = 0 or [enrollment\_eligib\_arm\_1][eadaily] = "" )}

---

Plan for a daily outpatient oral loop diuretic regimen upon hospital discharge: [enrollment\_eligib\_arm\_1][eadaily]  
 {Branching logic (show if): [randyn] = 1 and [enrollment\_eligib\_arm\_1][eadaily] = 1}

---

Does the patient have end-stage renal disease requiring renal replacement therapy? :  
 [enrollment\_eligib\_arm\_1][earenal]  
 {Branching logic (show if): [randyn] = 1 and ([enrollment\_eligib\_arm\_1][earenal] = 1 or [enrollment\_eligib\_arm\_1][earenal] = "" )}

---

Does the patient have end-stage renal disease requiring renal replacement therapy? :  
 [enrollment\_eligib\_arm\_1][earenal]  
 {Branching logic (show if): [randyn] = 1 and [enrollment\_eligib\_arm\_1][earenal] = 0 and [enrollment\_eligib\_arm\_1][earenal] = "" }

---

Does the patient have a history of heart transplant or actively listed for heart transplant?:  
 [enrollment\_eligib\_arm\_1][ealvad]  
 {Branching logic (show if): [randyn] = 1 and ([enrollment\_eligib\_arm\_1][ealvad] = 1 or [enrollment\_eligib\_arm\_1][ealvad] = "" )}

---

---

Does the patient have a history of heart transplant or actively listed for heart transplant?:

```
[enrollment_eligib_arm_1][ealvad]
{Branching logic (show if): [randyn] = 1 and [enrollment_eligib_arm_1][ealvad] = 0 and
[enrollment_eligib_arm_1][ealvad] ""}
```

---

Does the patient have an implanted LVAD or implant anticipated < 3 months?: [enrollment\_eligib\_arm\_1][eaimplv]

```
{Branching logic (show if): [randyn] = 1 and ([enrollment_eligib_arm_1][eaimplv] = 1 or
[enrollment_eligib_arm_1][eaimplv] = "")}
```

---

Does the patient have an implanted LVAD or implant anticipated < 3 months?: [enrollment\_eligib\_arm\_1][eaimplv]

```
{Branching logic (show if): [randyn] = 1 and [enrollment_eligib_arm_1][eaimplv] = 0 and
[enrollment_eligib_arm_1][eaimplv] ""}
```

---

Is the patient pregnant or nursing?: [enrollment\_eligib\_arm\_1][eapreg]

```
{Branching logic (show if): [randyn] = 1 and ([enrollment_eligib_arm_1][eapreg] = 1 or
[enrollment_eligib_arm_1][eapreg] = "")}
```

---

Is the patient pregnant or nursing?: [enrollment\_eligib\_arm\_1][eapreg]

```
{Branching logic (show if): [randyn] = 1 and [enrollment_eligib_arm_1][eapreg] = 0 and
[enrollment_eligib_arm_1][eapreg] ""}
```

---

Does the patient have a malignancy or other non-cardiac condition limiting life expectancy to < 12 months?:

```
[enrollment_eligib_arm_1][eamalig]
{Branching logic (show if): [randyn] = 1 and ([enrollment_eligib_arm_1][eamalig] = 1 or
[enrollment_eligib_arm_1][eamalig] = "")}
```

---

Does the patient have a malignancy or other non-cardiac condition limiting life expectancy to < 12 months?:

```
[enrollment_eligib_arm_1][eamalig]
{Branching logic (show if): [randyn] = 1 and [enrollment_eligib_arm_1][eamalig] = 0 and
[enrollment_eligib_arm_1][eamalig] ""}
```

---

Does the patient have a known hypersensitivity of furosemide, torsemide or related medications?:

```
[enrollment_eligib_arm_1][eahyper]
{Branching logic (show if): [randyn] = 1 and ([enrollment_eligib_arm_1][eahyper] = 1 or
[enrollment_eligib_arm_1][eahyper] = "")}
```

---

Does the patient have a known hypersensitivity of furosemide, torsemide or related medications?:

```
[enrollment_eligib_arm_1][eahyper]
{Branching logic (show if): [randyn] = 1 and [enrollment_eligib_arm_1][eahyper] = 0 and
[enrollment_eligib_arm_1][eahyper] ""}
```

---

Age >= 18 at time of informed consent: dob - [enrollment\_eligib\_arm\_1][ddob] informed consent date -

```
[enrollment_eligib_arm_1][icdate]
{Branching logic (show if): [randyn] = 1 and (datediff([enrollment_eligib_arm_1][ddob],
[enrollment_eligib_arm_1][icdate], "y", "mdy") < 18 or datediff([enrollment_eligib_arm_1][ddob],
[enrollment_eligib_arm_1][icdate], "y", "mdy") = 0 or [enrollment_eligib_arm_1][ddob] = "" or
[enrollment_eligib_arm_1][icdate] = "")}
```

---

Age >= 18 at time of informed consent: dob - [enrollment\_eligib\_arm\_1][ddob] informed consent date -

```
[enrollment_eligib_arm_1][icdate]
{Branching logic (show if): [randyn] = 1 and datediff([enrollment_eligib_arm_1][ddob],
[enrollment_eligib_arm_1][icdate], "y", "mdy") >= 18}
```

---

At least one of the following must be green in addition to all above in order to meet randomizing criteria:

```
{Branching logic (show if): [randyn] = 1}
```

---

---

Left Ventricular Ejection Fraction, % <= 40 : [enrollment\_eligib\_arm\_1][ealvef]  
 {Branching logic (show if): [randyn] = 1 and (([enrollment\_eligib\_arm\_1][ealvef] > 40 or  
 [enrollment\_eligib\_arm\_1][ealvef] = "" )}

---

Left Ventricular Ejection Fraction, % <= 40 : [enrollment\_eligib\_arm\_1][ealvef]  
 {Branching logic (show if): [randyn] = 1 and [enrollment\_eligib\_arm\_1][ealvef] <= 40 and  
 [enrollment\_eligib\_arm\_1][ealvef] "" }

---

Highest NT-proBNP > upper reference level for current hospitalization:  
 NT-proBNP([enrollment\_eligib\_arm\_1][earesntp]) and Upper reference level([enrollment\_eligib\_arm\_1][earesntu])  
 {Branching logic (show if): [randyn] = 1 and (([enrollment\_eligib\_arm\_1][earesntp]\*1) <=  
 ([enrollment\_eligib\_arm\_1][earesntu]\*1) or [enrollment\_eligib\_arm\_1][earesntp] = "" or  
 [enrollment\_eligib\_arm\_1][earesntu]= "" )}

---

Highest NT-proBNP > upper reference level for current hospitalization:  
 NT-proBNP([enrollment\_eligib\_arm\_1][earesntp]) and Upper reference level([enrollment\_eligib\_arm\_1][earesntu])  
 {Branching logic (show if): [randyn] = 1 and (([enrollment\_eligib\_arm\_1][earesntp] \* 1) >  
 ([enrollment\_eligib\_arm\_1][earesntu] \* 1))}

---

Highest BNP > upper reference level for current hospitalization: BNP([enrollment\_eligib\_arm\_1][earesbnp]) and  
 Upper reference level([enrollment\_eligib\_arm\_1][earesbnu])  
 {Branching logic (show if): [randyn] = 1 and (([enrollment\_eligib\_arm\_1][earesbnp]\*1) <=  
 ([enrollment\_eligib\_arm\_1][earesbnu]\*1) or [enrollment\_eligib\_arm\_1][earesbnp] = "" or  
 [enrollment\_eligib\_arm\_1][earesbnu] = "" )}

---

Highest BNP > upper reference level for current hospitalization: BNP([enrollment\_eligib\_arm\_1][earesbnp]) and  
 Upper reference level([enrollment\_eligib\_arm\_1][earesbnu])  
 {Branching logic (show if): [randyn] = 1 and (([enrollment\_eligib\_arm\_1][earesbnp] \* 1) >  
 ([enrollment\_eligib\_arm\_1][earesbnu]\*1))}

---

Randomized treatment arm  
 {[randarm] radio}  
 {Branching logic (show if): [randyn] = 1 and  
 [enrollment\_eligib\_arm\_1][eahost] = 1 and  
 [enrollment\_eligib\_arm\_1][eahoshf] = 1 and  
 [enrollment\_eligib\_arm\_1][eadaily] = 1 and  
 (([enrollment\_eligib\_arm\_1][ealvef] <= 40 and  
 [enrollment\_eligib\_arm\_1][ealvef] "" ) or  
 ([enrollment\_eligib\_arm\_1][earesntp]\*1) >  
 ([enrollment\_eligib\_arm\_1][earesntu]\*1) or  
 ([enrollment\_eligib\_arm\_1][earesbnp]\*1) >  
 ([enrollment\_eligib\_arm\_1][earesbnu]\*1)) and  
 [enrollment\_eligib\_arm\_1][earenal] = 0 and  
 [enrollment\_eligib\_arm\_1][ealvad] = 0 and  
 [enrollment\_eligib\_arm\_1][eaimplv] = 0 and  
 [enrollment\_eligib\_arm\_1][eapreg] = 0 and  
 [enrollment\_eligib\_arm\_1][eamalig] = 0 and  
 [enrollment\_eligib\_arm\_1][eahyper] = 0 and  
 datediff([enrollment\_eligib\_arm\_1][ddob],  
 [enrollment\_eligib\_arm\_1][icdate], "y", "mdy") > 18}

---

- {Furosemide} Oral Furosemide  
 {Torsemide} Oral Torsemide

Form Save date and time  
 {[frmsvdt] text datetime\_mdy}

\_\_\_\_\_ (mm/dd/yyyy hh:mm)

---

Please save this form after randomizing the patient

```
{Branching logic (show if): [randyn] = 1 and [enrollment_eligib_arm_1][eahost] = 1 and
[enrollment_eligib_arm_1][eahoshf] = 1 and [enrollment_eligib_arm_1][eadaily] = 1 and
((([enrollment_eligib_arm_1][ealvef] <= 40 and [enrollment_eligib_arm_1][ealvef] "")) or
([enrollment_eligib_arm_1][earesntp]*1) > ([enrollment_eligib_arm_1][earesntu]*1) or
([enrollment_eligib_arm_1][earesbnp]*1) > ([enrollment_eligib_arm_1][earesbnu]*1)) and
[enrollment_eligib_arm_1][earenal] = 0 and [enrollment_eligib_arm_1][ealvad] = 0 and
[enrollment_eligib_arm_1][eaimplv] = 0 and [enrollment_eligib_arm_1][eapreg] = 0 and
[enrollment_eligib_arm_1][eamalig] = 0 and [enrollment_eligib_arm_1][eahyper] = 0 and
datediff([enrollment_eligib_arm_1][ddob], [enrollment_eligib_arm_1][icdate], "y", "mdy") > 18}
```

# TRANSFORM\_annotated

---

Was the first dose of study drug administered prior to discharge?  
{[sdaadm] radio}

- {1} Yes  
 {0} No

---

Reason patient was NOT given first dose: (check one)  
{[sdanotg] radio}  
{Branching logic (show if): [sdaadm] = 0 and [sdaadm] ""}

- {1} Patient was discharged prior to first dose  
 {2} Not clinically indicated  
 {3} Patient refused  
 {4} Patient died

---

Date (time) of first dose after randomization  
{[sdadate] text datetime\_mdy}  
{Branching logic (show if): [sdaadm] = 1}

\_\_\_\_\_  
(mm/dd/yyyy hh:mm)

---

Medication name  
{[sdaname] radio}  
{Branching logic (show if): [sdaadm] = 1}

- {1} Furosemide (oral)  
 {2} Torsemide (oral)

---

Total daily dose prescribed, mg  
{[sdafirst] text float}  
{Branching logic (show if): [sdaadm] = 1}

\_\_\_\_\_  
(ex. patient prescribed 20mg, 2x day = 40mg)

**TRANSFORM\_annotated**

Date of admission  
{[ihadmn] text date\_mdy}

\_\_\_\_\_  
(mm/dd/yyyy)

Date of discharge  
{[ihdsch] text date\_mdy}

\_\_\_\_\_  
(mm/dd/yyyy)

Primary inpatient care team at the time of randomization (i.e., not consult services):  
{[ihinpcr] radio}

- {1} Cardiology (e.g., heart failure service, general cardiology service, other cardiology service)
- {2} Hospitalist, internal medicine, or family medicine
- {3} Surgery (e.g., cardiothoracic surgery service, other surgical service)
- {4} Other

Insurance Payors  
{[ihinspyr] checkbox}

- {1} Private Health Insurance
- {2} Medicare
- {3} Medicaid
- {4} Military Health Care
- {5} State-specific Plan (non-Medicaid)
- {6} Indian Health Services
- {7} Other US Insurance
- {8} None/Self Pay  
(check all that apply)

**NDI search information**

Middle Initial  
{[dmidin] text}

\_\_\_\_\_  
(Please provide MI. If the participant does not have a middle initial, please write "none". If the middle initial is not known by the site team, please write "UNK". If the participant has multiple middle names, provide the multiple middle initials.)

What is the patient's current marital status?  
{[dmarst] radio}

- {1} Married or living as married
- {2} Divorced
- {3} Separated
- {4} Widowed
- {5} Never married/Annulled/Single
- {6} Prefers not to answer

# TRANSFORM\_annotated

---

Does the patient have a history of HF prior to current hospitalization?  
{[hfhist] radio}

{1} Yes  
 {0} No

---

Duration of HF diagnosis prior to current hospitalization  
{[hfddtyn] radio}  
{Branching logic (show if): [hfhist] = 1}

{1} < = 30 days Duration  
 {2} >30 days and < =12 months Duration  
 {3} >12 months Duration  
 {4} UNK

---

Was the patient hospitalized for HF within 12 months prior to current hospitalization?  
{[hfhosp] radio}  
{Branching logic (show if): [hfhist] = 1}

{1} Yes  
 {0} No  
 {2} UNK

---

What is the patient's primary HF etiology?  
{[hfetilgy] radio}

{1} Ischemic  
 {2} Non-ischemic  
 {3} UNK

---

NYHA class at current hospital admission  
{[hfnyhadm] radio}

{1} I  
 {2} II  
 {3} III  
 {4} IV  
 {5} UNK

---

NYHA class at time of randomization (or most recent prior to randomization)  
{[hfnyhrdm] radio}

{1} I  
 {2} II  
 {3} III  
 {4} IV  
 {5} UNK

**TRANSFORM\_annotated**


---

Does the patient have a medical history of any of the following?

---

Atrial fibrillation or atrial flutter  
{[gmaf] radio}  {1} Yes  
 {0} No

---

Diabetes mellitus  
{[gm dm] radio}  {1} Yes  
 {0} No

---

Chronic kidney disease  
{[gmckd] radio}  {1} Yes  
 {0} No

---

Hypertension  
{[gmh ypt e] radio}  {1} Yes  
 {0} No

---

Hypercholesterolemia  
{[gmh ypc l] radio}  {1} Yes  
 {0} No

---

Peripheral Artery Disease  
{[gmpad] radio}  {1} Yes  
 {0} No

---

Coronary Artery Disease  
{[gmcad] radio}  {1} Yes  
 {0} No

---

Myocardial infarction  
{[gm mi] radio}  {1} Yes  
 {0} No

---

Prior PCI  
{[gmppci] radio}  {1} Yes  
 {0} No

---

Prior CABG  
{[gm pcabg] radio}  {1} Yes  
 {0} No

---

Chronic lung disease (including COPD)  
{[gm cl d] radio}  {1} Yes  
 {0} No

---

Stroke / TIA  
{[gm stroke] radio}  {1} Yes  
 {0} No

---

Cigarette smoking  
{[gm smoke] radio}  {1} Current smoker  
 {2} Former smoker  
 {3} Never smoked

---

Does the patient have any of the following devices currently implanted?

---

Implantable cardioverter defibrillator (ICD)  
{[gm icd] radio}  {1} Yes  
 {0} No

---

Cardiac resynchronization therapy (CRT)  
{[gm crt] radio}  {1} Yes  
 {0} No

---

**TRANSFORM\_annotated**

## Loop diuretic use PRIOR to current hospitalization

Was the patient actively prescribed an oral loop diuretic prior to current hospital admission?  
 {[ldprior] radio}  {1} Yes  {0} No

Most recent oral loop diuretic prescribed  
 {[ldpmdnm] radio}  {1} furosemide (Lasix)  
 {Branching logic (show if): [ldprior] = 1}  {2} torsemide (Demadex)  
 {3} bumetanide (Bumex)  
 {4} ethacrynic acid (Edecrin)

Total daily dose prescribed, mg  
 {[ldpdose] text float} \_\_\_\_\_  
 {Branching logic (show if): [ldprior] = 1}

{[ldpasnd] radio}  {1} As Needed (PRN)  
 {Branching logic (show if): [ldprior] = 1}

## Loop diuretic use DURING current hospitalization

Did the patient receive IV loop diuretic during current hospitalization prior to randomization?  
 {[lddur] radio}  {1} Yes  {0} No

What is the most recent IV loop diuretic the patient received prior to randomization?  
 {[ldmdnm] radio}  {1} furosemide (Lasix)  
 {Branching logic (show if): [lddur] = 1}  {2} torsemide (Demadex)  
 {3} bumetanide (Bumex)  
 {4} ethacrynic acid (Edecrin)

Maximum daily dose received, mg  
 {[lddddose] text float} \_\_\_\_\_  
 {Branching logic (show if): [lddur] = 1}

**TRANSFORM\_annotated**


---

Is the patient currently taking any of the following medications at the time of randomization?

---

Angiotensin converting enzyme (ACE) inhibitor  
{[bmaceyn] radio}  {1} Yes  
 {0} No

---

{[bmacesp] radio}  
{Branching logic (show if): [bmaceyn] = 1}

{1} benazepril [Lotensin]  
 {2} captopril [Capoten]  
 {3} enalapril [Epaned, Vasotec, Renitec]  
 {4} fosinopril [Monopril]  
 {5} lisinopril [Prinivil, Zestril]  
 {6} moexipril [Univasc]  
 {7} perindopril [Aceon]  
 {8} quinapril [Accupril]  
 {9} ramipril [Altace]  
 {10} trandolapril [Mavik]  
 {11} other ACE inhibitor

---

Angiotensin receptor blocker (ARB)  
{[bmarbyn] radio}  {1} Yes  
 {0} No

---

{[bmarbsp] radio}  
{Branching logic (show if): [bmarbyn] = 1}

{1} candesartan [Atacand]  
 {2} eprosartan [Teveten]  
 {3} irbesartan [Avapro]  
 {4} losartan [Cozaar]  
 {5} olmesartan [Benicar]  
 {6} telmisartan [Micardis]  
 {7} valsartan [Diovan]  
 {8} other ARB

---

Angiotensin receptor-neprilysin inhibitor (ARNi)  
{[bmarnisp] radio}  {1} sacubitril/valsartan [Entresto]

---

Aldosterone antagonists / Mineralocorticoid receptor  
antagonist (MRA) (e.g., spironolactone, eplerenone)  
{[bmmrayn] radio}  {1} Yes  
 {0} No

---

{[bmmrasp] radio}  
{Branching logic (show if): [bmmrayn] = 1}

{1} eplerenone [Inspra]  
 {2} spironolactone [Aldactone]  
 {3} other MRA

---

Beta blocker  
{[bmbetayn] radio}  {1} Yes  
 {0} No

---

{[bmbetasp] radio} {Branching logic (show if): [bmbetayn] = 1}	<input type="radio"/> {1} acebutolol [Sectral] <input type="radio"/> {2} atenolol [Senormin, Tenormin] <input type="radio"/> {3} betaxolol <input type="radio"/> {4} bisoprolol [Zebeta] <input type="radio"/> {5} carvedilol [Coreg] <input type="radio"/> {6} labetalol [Trandate] <input type="radio"/> {7} metoprolol succinate [Toprol XL] <input type="radio"/> {8} metoprolol tartrate [Lopressor] <input type="radio"/> {9} nadolol [Corgard] <input type="radio"/> {10} nebivolol [Bystolic] <input type="radio"/> penbutolol [Levato], {11,penbutolol [Levato]} <input type="radio"/> {12} pindolol [Visken] <input type="radio"/> {13} propranolol [Inderal, Innopran] <input type="radio"/> {14} other beta blocker
Long-acting nitrate {[bmlanyn] radio}	<input type="radio"/> {1} Yes <input type="radio"/> {0} No
{[bmlansp] radio} {Branching logic (show if): [bmlanyn] = 1}	<input type="radio"/> {1} isosorbide dinitrate [dilatrane-SR, isordil, isordil titradose, isosrbid dinitrate] <input type="radio"/> {2} isosorbide mononitrate [imdur, ismo, monoket] <input type="radio"/> {3} other long-acting nitrate
Thiazide diuretics {[bmthiayn] radio}	<input type="radio"/> {1} Yes <input type="radio"/> {0} No
{[bmthiasp] radio} {Branching logic (show if): [bmthiayn] = 1}	<input type="radio"/> {1} chlorothiazide [Diuril] <input type="radio"/> {2} chlorthalidone [Thalitone] <input type="radio"/> {3} hydrochlorothiazide [Microzide] <input type="radio"/> {4} indapamide <input type="radio"/> {5} metolazone [Zaroxolyn] <input type="radio"/> {6} other thiazide diuretics
Intravenous inotrope / vasopressor {[bminotyn] radio}	<input type="radio"/> {1} Yes <input type="radio"/> {0} No
{[bminotsp] checkbox} {Branching logic (show if): [bminotyn] = 1}	<input type="checkbox"/> Dobutamine, {1,Dobutamine} <input type="checkbox"/> {2} Dopamine <input type="checkbox"/> {3} Milrinone <input type="checkbox"/> {4} Other inotrope/vasopressor
Oral Anticoagulant {[bmantiyn] radio}	<input type="radio"/> {1} Yes <input type="radio"/> {0} No
{[bmantisp] radio} {Branching logic (show if): [bmantiyn] = 1}	<input type="radio"/> {1} warfarin (Coumadin) <input type="radio"/> {2} direct oral anticoagulant [examples: Rivaroxaban, Apixaban, Edoxaban, Dabigatran]
Other heart failure medications {[bmdigoy2] checkbox}	<input type="checkbox"/> {1} digoxin [Lanoxin, Digox] <input type="checkbox"/> {2} hydralazine [Apresoline] <input type="checkbox"/> {3} ivabradine [Corlanor]
Retired question: Other heart failure medications {[bmdigoy] radio}	<input type="radio"/> {1} digoxin [Lanoxin, Digox] <input type="radio"/> {2} hydralazine [Apresoline] <input type="radio"/> {3} ivabradine [Corlanor]

---

SGLT-2 inhibitor (e.g., canagliflozin,  
dapagliflozin, empagliflozin)  
{[bmspltn] radio}

- {1} Yes  
 {0} No

---

{[bmsgltsp] radio}  
{Branching logic (show if): [bmspltn] = 1}

- {1} canagliflozin [Invokana]  
 {2} dapagliflozin [Farxiga]  
 {3} empagliflozin [Jardiance]  
 {4} Other SGLT-2 inhibitor

---

Other medications  
{[bmglp1] checkbox}

- {1} GLP-1 agonist (e.g., dulaglutide, exenatide,  
liraglutide)  
 {2} Oral glucose lowering therapy excluding SGLT-2  
inhibitor and GLP-1 agonist  
 {3} Insulin therapy  
 {4} Aspirin  
 {5} Other antiplatelet agent excluding aspirin  
[examples: Clopidogrel, Ticagrelor, Prasugrel]  
 {6} Antiarrhythmic [not including beta-blockers]  
 {7} Statin  
 {8} Non-statin lipid lowering therapy

# TRANSFORM\_annotated

---

## Status information at discharge

---

What is the patient's disposition at discharge?  
 {[disstat] radio}

- {1} Home
- {2} Hospice - Home
- {3} Hospice - Health Care Facility
- {4} Acute Care Facility
- {5} Skilled Nursing Facility
- {6} Inpatient Rehabilitation Facility
- {7} Long Term Care Hospital
- {8} Intermediate Care Facility
- {9} Other institution not listed above
- {10} Died in hospital prior to discharge
- {11} Left Against Medical Advice

---

## Discharge institution

Name

{[disname] text}

{Branching logic (show if): [disstat] = 3 or  
 [disstat] = 4 or [disstat] = 5 or [disstat] = 6 or  
 [disstat] = 7 or [disstat] = 8 or [disstat] = 9}

---

City

{[discity] text}

{Branching logic (show if): [disstat] = 3 or  
 [disstat] = 4 or [disstat] = 5 or [disstat] = 6 or  
 [disstat] = 7 or [disstat] = 8 or [disstat] = 9}

---

State

{[disstate] text}

{Branching logic (show if): [disstat] = 3 or  
 [disstat] = 4 or [disstat] = 5 or [disstat] = 6 or  
 [disstat] = 7 or [disstat] = 8 or [disstat] = 9}

---



---

## Date of Death

Date of death

{[disdod] text date\_mdy}

{Branching logic (show if): [disstat] = 10}

---

(mm/dd/yyyy)

**TRANSFORM\_annotated**


---

Date the informed consent was sent to the Call Center

{[adinfcon] text date\_mdy}

\_\_\_\_\_ (mm/dd/yyyy)

---

Date the medical release was sent to the Call Center

{[admedrls] text date\_mdy}

\_\_\_\_\_ (mm/dd/yyyy)

---

Date the patient contact form was sent to the Call Center

{[adpatcon] text date\_mdy}

\_\_\_\_\_ (mm/dd/yyyy)

---

Date the discharge instructions were sent to the Call Center

{[adinstr] text date\_mdy}

{Branching logic (show if):

[gen\_baseline\_rand\_arm\_1][disdod] = ""}

\_\_\_\_\_ (mm/dd/yyyy)

---

Date the death summary was sent to the Call Center

{[addthsum] text date\_mdy}

{Branching logic (show if):

[gen\_baseline\_rand\_arm\_1][disdod] ""}

\_\_\_\_\_ (mm/dd/yyyy)

---

What was the patient's study status at discharge?

{[adstat] radio}

- {1} Continuing in study with full participation
- {2} Continuing in study with reduced level of participation
- {3} Withdrew consent for all follow-up
- 

For reduced level of participation, please indicate contact level

{[adcall] radio}

{Branching logic (show if): [adstat] = 2}

- {1} Reduced call schedule (only call at 12 months)
- {2} Do not call - medical record follow-up only

# TRANSFORM\_annotated

---

I confirm that all data supplied in this case report form are correct.

---

PI Signature  
{[pisig] file signature}

---

(PI only)



**ToRsemide compArisoN with furoSemide FOR  
Management of Heart Failure (TRANSFORM-HF)**

An approximately 6000-patient, randomized, unblinded, two-arm, multicenter clinical trial comparing torsemide with furosemide among patients hospitalized for heart failure.

**Case Report Form  
Instructions**

**26-Jul-2019**

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TRANSFORM eCRF Instructions: Summary of Changes			
Version	Section	Page #	Change
2.0	Enrollment And Eligibility Assessments	8	Updated screen shot to show new warning concerning patient id number format
2.0	Enrollment And Eligibility Assessments	8-9	If site responds they enroll at more than one hospital, a drop down list is now available instead of free-text. New screen shot and new instructions
2.0	Rand	19	Additional note about reminder to save form at the bottom
2.0	Study Drug Administration	20	Added a screen shot with updated question text for Date (time) of first dose after randomization
2.0	Current Hospitalization And Other Information	21	Added new question Primary inpatient care team at the time of randomization (i.e., not consult services)
2.0	Current Hospitalization And Other Information	21	Updated the Middle Initial field to include a field note about how to complete the field
2.0	Baseline Medications	27-28	Updated screen shot to show retired question and new multi select question for Other heart failure medications. Now it is a select all question
2.0	Baseline Medications	27	Updated Anticoagulant to include the word Oral Also added, examples to the Aldosterone antagonists/Mineralocorticoid receptor antagonist and the SGLT-2 inhibitor questions

## Logging in to REDCap

URL: <https://redcap.duke.edu/>

**REDCap™**

Log In

 **Duke Office of Clinical Research**  
Duke University School of Medicine

**Upgrade Notice:** The REDCap system was upgraded to version 8.1. A full list of new features, changes, and improvements found in this version can be found [here](#).

Weekly office hours are held every Tuesday in the Medical Center Library & Archives **Seeley G. Mudd Building** conference room **212C** from 10am-11am and the first Thursday of the month from 10am-11am in DMP 2W96.

Please contact us at [redcap-docr@duke.edu](mailto:redcap-docr@duke.edu), with any questions.

Please log in with your user name and password. If you are having trouble logging in, please contact [DOCR REDCap Support](#).

Username:

Password:

Log In [Forgot your password?](#)

By logging into Duke's REDCap instance, you agree to the [Secure Usage Agreement](#).

The Duke REDCap Secure Usage Policy can be found by clicking [here](#).

**Need to recover your password?** [Password recovery is available anytime](#)

Internal Duke Users: If you have forgotten your DHE/NetID password, you can recover it [here](#).

External Duke Users: If you have forgotten your DTMI ID or password, you can recover it [here](#).

System will time out after 10 minutes of idle.

## Accessing the TRANSFORM-HF Study

Go to the **My Projects** tab and click on **TRANSFORM**.

of new features, changes, and improvements found in this version can be found [here](#).

Weekly office hours are held every Tuesday in the Medical Center Library & Archives **Seeley G. Mudd Building** conference room **212C** from 10am-11am and the first Thursday of the month from 10am-11am in DMP 2W96.

Please contact us at [redcap-docr@duke.edu](mailto:redcap-docr@duke.edu), with any questions.

Listed below are the REDCap projects to which you currently have access. Click the project title to open the project. [Read more](#)  
To review which users still have access to your projects, visit the [User Access Dashboard](#).

My Projects		Organize		Filter projects by title		
Project Title	Records	Fields	Instrument	Type	Status	
<b>Unorganized Projects</b> (4)						
<b>TRANSFORM</b> ←	3	169	17 forms			
Marinus EEG Imaging	7	29	7 forms			
CDM QC1 EPITOMISE	12	434	17 forms			
SPIRRIT	0	2	1 form			

## Data Entry

- 1) Open REDCap and go to **Add/Edit Records**.
- 2) To create a new patient, click in the “Enter a new or existing Patient ID Number” text box and enter a new subject id. **The subject ID is your 3-digit site number, dash, and the next 3-digit incremental subject number for your site. For example, if your site number is 999, the first patient enrolled at your site is 999-001. The next patient is 999-002, and so on.** Please note that leading zeroes must be included. If you accidentally enter the wrong number immediately stop any further data entry and contact site management or the data manager for assistance.
- 3) A new subject record will be created for the subject.
- 4) **Patient ID Number** will auto-populate at the top of each form.
- 5) Enter all required forms for the visit.
- 6) When returning to the subject for future data entry, click on **Add/Edit Records** and use the “**Choose an existing Patient ID Number**” dropdown box to select and return to your subject or enter the existing id number in the “Enter a new or existing Patient ID Number” box.




The screenshot shows the REDCap interface for the Duke Office of Clinical Research. The left sidebar contains navigation options: 'My Projects', 'Project Home', 'Project Setup', 'Data Collection', 'Record Status Dashboard', 'Add / Edit Records' (highlighted with a red arrow), and 'Applications'. The main content area displays the 'TRANSFORM' project status and navigation buttons for 'Project Home', 'Project Setup', 'Other Functionality', and 'Project Revision History'. The project status is 'Development' and 'Completed steps 0 of 9'.

### Add / Edit Records

You may view an existing record/response by selecting it from the drop-down lists below. To create a new record/response, type a new value in the text box below and hit Tab or Enter. To quickly find a record without using the drop-downs, the text box will auto-populate with existing record names as you begin to type in it, allowing you to select it.

Total records: 0	
Choose an existing Patient ID Number	<input type="text" value="-- select record --"/>
Enter a new or existing Patient ID Number	<input type="text"/>



## Record Home Page

The grid below displays the form-by-form progress of data entered for the currently selected record. You may click on the colored status icons to access that form/event.

### Legend for status icons:

- Incomplete  Incomplete (no data saved) ?
- Unverified
- Complete

[Choose action for record](#)

Legend for status icons

✓ Patient ID Number 999-001 successfully edited

Patient ID Number 999-001

Visits

Data Collection Instrument	Enrollment & Eligibility	Pre-randomization Questions	Gen. Baseline, Rand, & Post	Administrative Forms
Enrollment And Eligibility Assessments	<input checked="" type="radio"/>			
Demographics	<input checked="" type="radio"/>			
The Kansas City Cardiomyopathy Questionnaire KCCQ		<input type="radio"/>		
PHQ2		<input type="radio"/>		
Prerandomization Dosing Strategy		<input type="radio"/>		
Vital Signs			<input type="radio"/>	
Labs			<input type="radio"/>	
Randomization			<input type="radio"/>	
Study Drug Administration			<input type="radio"/>	
Current Hospitalization And Other Information			<input type="radio"/>	
Hf Characteristics			<input type="radio"/>	
General Medical History			<input type="radio"/>	
Loop Diuretic Use			<input type="radio"/>	
Baseline Medications			<input type="radio"/>	
Discharge Disposition			<input type="radio"/>	
Administrative Fields				<input type="radio"/>
PI Signature				<input type="radio"/>

eCRF pages

**Visits** - across the top from left to right

Enrollment & Eligibility – Completed from time of consent to determination of inclusion.

Pre-randomization Questions – Completed after inclusion but prior to randomization.

Gen. Baseline, Rand, & Post – General Baseline, Randomization, and Post randomization questions

Administrative Forms – Forms capturing dates for providing information to the call center and also collecting the patient’s study status at discharge

**eCRF pages** - on the left from top to bottom

**Legend for status icons** – Unverified, Complete, and Incomplete from the Form Status section of each form (see **Workflow for Saving Data** section on page 6)

**Legend for status icons:**

- Incomplete  Incomplete (no data saved) - Unverified
- Complete

## Workflow for Saving Data

A **Form Status** section can be found at the bottom of each form.

Does the patient have a known hypersensitivity of furosemide, torsemide or related medications?  Yes  No reset

**Form Status**

Complete?  Incomplete  Complete

Lock this record for this form?  Lock  
If locked, no user will be able to edit this record on this form until someone with Lock/Unlock privileges unlocks it.

- Save & Go To Next Form
- Save & Exit Record
- Save & Go To Next Record

### Complete?

- Unverified – This option is not being used for this study
- Complete – **select when data entry on a form has been completed**
- Incomplete – select only if partial data entry on a form was performed

You will also be prompted to select from the following options:

- **Save & Exit Form** – brings you back to screen where you can enroll another subject OR continue entering data for current subject
- **Save & Stay** – saves data on current form and keeps you in current form and subject
- **Save & Go To Next Form** – saves data on current form and sends you to next form in visit for subject (**recommended**)
- **Save and Exit Record** - saves data on current form and goes back to the Add/Edit records
- **Save and Go To Next Record** - saves data on current form and goes to the next patient record

**You MUST click one of the options to save your record!**

**The form status creates the colored traffic lights on the Record Home Page.**

## Enrollment and Eligibility Assessments

Complete this form at [Enrollment and Eligibility](#). A warning has been added to check the format of the Patient ID Number.

**Please note that all questions must be answered per protocol to meet the requirements of inclusion/exclusion before the randomization button is visible on the randomization page.**

**Patient ID Number** 242-001  
To rename the record, see the record action drop-down at top of the [Record Home Page](#)

Please review the format of the Patient ID Number above. If it does not meet the XXX-XXX format where the first 3 digits are site number and the 3 digits after the dash is the sequential patient number, please inform the site management team at Transform\_HF@dm.duke.edu so that a correction can be made

**Does your site enroll patients at more than one hospital?**  Yes  No

**Date (time) of informed consent:** 07-16-2019 10:28  M-D-Y H:M  
mm/dd/yyyy hh:mm

**Patient hospitalized for >= 24 hours or over a change in calendar date?**  Yes  No

**Patient hospitalized with:**  Worsening of chronic heart failure or new diagnosis of heart failure  
 No heart failure

**Is there a plan for a daily outpatient oral loop diuretic regimen upon hospital discharge?**  Yes  No

**Is there a left ventricular ejection fraction available (by any modality) within 24 months prior to and including the current hospitalization?**  Yes  No

**Is an NT-proBNP or BNP result available from the current hospitalization?**  Yes  No

**Patient ID Number:** The patient ID created upon enrollment is auto-populated at the top of each form.

**Does your site enroll patients at more than one hospital?** Only select yes if your site enrolls patients at more than one hospital for the TRANSFORM-HF study. If you select yes, you will be prompted to select the name of the hospital where this patient was enrolled. Please let your site management team know if your institution is not listed.

Event Name: <b>Enrollment &amp; Eligibility</b>	
<b>Patient ID Number</b>	9999-004 <small>To rename the record, see the record action drop-down at top of the <a href="#">Record Home Page</a>.</small>
<b>Please review the format of the Patient ID Number above. If it does not meet the XXX-XXX format where the first 3 digits are site number and the 3 digits after the dash is the sequential patient number, please inform the site management team at Transform_HF@dm.duke.edu so that a correction can be made</b>	
<b>Does your site enroll patients at more than one hospital?</b>	<input checked="" type="radio"/> Yes <input type="radio"/> No <span style="float: right;">reset</span>
<b>What is the name of the hospital where this patient was enrolled?</b>	<input type="text"/> <span style="float: right;">reset</span>
<b>Retired Question: What is the name of the hospital where this patient was enrolled?</b>	<input type="text"/>
<b>Date (time) of informed consent:</b>	<input type="text"/> <input type="button" value="Now"/> M-D-Y H:M <small>mm/dd/yyyy hh:mm</small>
<b>Patient hospitalized for &gt;= 24 hours or over a change in calendar</b>	<input checked="" type="radio"/> Yes

**Is there a left ventricular ejection fraction available (by any modality) within 24 months prior to and including the current hospitalization?** If yes, you will be prompted to provide *Left Ventricular Ejection Fraction* in %. This should be the most recent value by any cardiac imaging modality. When the result is reported as a range in the medical record source, please record the average and round up if the tenths place is 0.5 or higher. For example: If the range is 30-35%, the average is 32.5% so an EF of 33% will be recorded in the CRF. Or, if the range is 30-40%, the average is 35.0% so an EF of 35% will be recorded in the CRF.

**Is an NT-proBNP or BNP result available from the current hospitalization?** If yes, you will be prompted to check which lab result is available, NT-proBNP and/or BNP, and enter the highest value for the current hospitalization along with the upper reference limit at your local laboratory. If multiple proBNP/BNP labs are drawn during the current hospitalization, the highest value should be used for purposes of eligibility and recorded in the CRF.

## Enrollment and Eligibility Assessments – Continued

Please note that all questions on this form must be answered per protocol to meet the requirements of inclusion/exclusion before the randomization button is visible on the randomization page.

Does the patient have end-stage renal disease requiring renal replacement therapy?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">reset</a>
Does the patient have a history of heart transplant or actively listed for heart transplant?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">reset</a>
Does the patient have an implanted LVAD or implant anticipated < 3 months?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">reset</a>
Is the patient pregnant or nursing?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">reset</a>
Does the patient have a malignancy or other non-cardiac condition limiting life expectancy to < 12 months?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">reset</a>
Does the patient have a known hypersensitivity of furosemide, torsemide or related medications?	<input type="radio"/> Yes <input type="radio"/> No	<a href="#">reset</a>

## Demographics

Complete this form at [Enrollment & Eligibility](#).

<b>Date of Birth</b>	<input type="text"/> <input type="button" value="Today"/> M-D-Y mm/dd/yyyy
<b>Sex</b>	<input type="radio"/> Female <input type="radio"/> Male <a href="#">reset</a>
<b>Race</b>	<input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Chinese <input type="checkbox"/> Japanese <input type="checkbox"/> Filipino <input type="checkbox"/> Other Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> Native Hawaiian <input type="checkbox"/> Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Other <input type="checkbox"/> check all that apply
<b>Ethnicity</b>	<input type="radio"/> Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <a href="#">reset</a>

**Date of Birth:** The DOB must be answered per protocol to meet the requirements of inclusion/exclusion before the randomization button is visible on the randomization page.

**Sex:** Sex at birth.

**Race:** Check all that apply.

Definitions for **Race** and **Ethnicity** (Note: some categories are expanded from the standard for NDI search purposes):

- **American Indian or Alaska Native:** A person having origins in any of the original peoples of North and South America (including Central America), and who maintains tribal affiliation or community attachment.
- **Chinese:** A person having origins in any of the original peoples of China.
- **Japanese:** A person having origins in any of the original peoples of Japan.
- **Filipino:** A person having origins in any of the original peoples of the Philippines.
- **Other Asian:** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent not including China, Japan, and Philippine Islands; for example, Cambodia, India, Korea, Malaysia, Pakistan, Thailand, and Vietnam.
- **Black or African American:** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."

- **Native Hawaiian:** A person having origins in any of the original peoples of Hawaii.
- **Pacific Islander:** A person having origins in any of the original peoples of Guam, Samoa, or other Pacific Islands not including Hawaii.
- **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
  
- **Hispanic or Latino:** A person of Cuban, Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."

## The Kansas City Cardiomyopathy Questionnaire KCCQ

Complete this form at [Pre-randomization Questions](#). This questionnaire should be administered the same day of and prior to randomization but the form in REDCap should not be data entered until the participant is randomized.

Was the KCCQ administered?  Yes  No [reset](#)

### Was the KCCQ administered?

- If yes, you will be prompted to complete the Kansas City Cardiomyopathy Questionnaire.
- If no, you will be prompted to provide the reason.

## PHQ2

Complete this form at [Pre-randomization Questions](#). This questionnaire should be administered the same day of and prior to randomization but the form in REDCap should not be data entered until the participant is randomized.

Was the PHQ-2 administered?  Yes  No [reset](#)

### Was the PHQ-2 administered?

- If yes, you will be prompted to provide the following:

Was this data collected prior to randomization?  Yes  No [reset](#)



Over the past 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
Little interest or pleasure in doing things <input type="radio"/> <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Feeling down, depressed or hopeless <input type="radio"/> <input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

- If no, you will be prompted to provide the reason.

## Prerandomization Dosing Strategy

Complete this form at [Pre-randomization Questions](#). This form should be completed prior to randomization.

<b>What is the planned starting dose if the patient is randomized to:</b>	
<b>Furosemide Dose</b>	
<b>Total oral daily dose, mg</b> 	<input type="text"/>
<b>Torsemide Dose</b>	
<b>Total oral daily dose, mg</b> 	<input type="text"/>

**Total oral daily dose:** enter in mg the anticipated total daily dose that the patient would be prescribed for Furosemide and Torsemide if the patient is randomized to that treatment arm.

## Vital Signs

Complete this form at Gen. Baseline, Rand, & Post.

**Enter the most recent vital sign values that are closest to and prior to randomization.**

<b>Systolic blood pressure, mmHg</b>	<input type="text"/>
<b>Diastolic blood pressure, mmHg</b>	<input type="text"/>
<b>Heart rate, BPM</b>	<input type="text"/>
<hr/>	
<b>Height</b>	<input type="text"/>
	<input type="radio"/> Inches <input type="radio"/> Centimeters
	<a href="#">reset</a>
<hr/>	
<b>Weight</b>	<input type="text"/>
	<input type="radio"/> Pounds <input type="radio"/> Kilograms
	<a href="#">reset</a>

**Systolic blood pressure:** Enter in mmHg.

**Diastolic blood pressure:** Enter in mmHg.

**Heart rate:** Enter in BPM.

**Height:** Enter number and select unit. Height documented in the patient's medical record or self-reported is acceptable.

**Weight:** Enter number and select unit.

## Labs

Complete this form at Gen. Baseline, Rand, & Post.

**Enter the most recent lab values that are closest to and prior to randomization.**

<b>Sodium, mEq/L (equivalent to mmol/L)</b>	<input type="text"/>	<input type="radio"/> mg/dL <input type="radio"/> mmol/L	reset
<b>Potassium, mEq/L (equivalent to mmol/L)</b>	<input type="text"/>		
<b>Blood urea nitrogen (BUN)</b>	<input type="text"/>	<input type="radio"/> mg/dL <input type="radio"/> micromoles/L	reset
<b>Serum Creatinine</b>	<input type="text"/>	<input type="radio"/> g/dL <input type="radio"/> g/L	reset
<b>Hemoglobin</b>	<input type="text"/>		

**Sodium:** Enter in mEq/L (equivalent to mmol/L).

**Potassium:** Enter in mEq/L (equivalent to mmol/L).

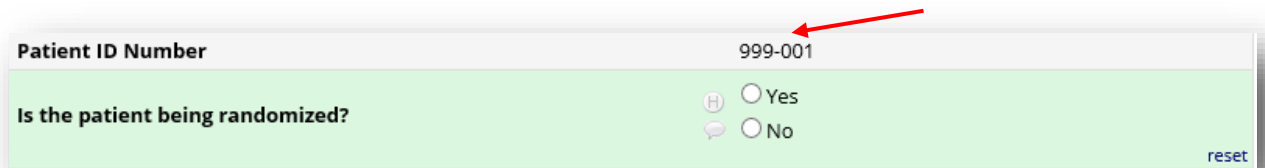
**Blood urea nitrogen (BUN):** Enter number and select unit.

**Serum Creatinine:** Enter number and select unit.

**Hemoglobin:** Enter number and select unit.

## Randomization

Complete this form at Gen. Baseline, Rand, & Post.



<b>Patient ID Number</b>	999-001
<b>Is the patient being randomized?</b>	<input type="radio"/> Yes <input type="radio"/> No
<a href="#">reset</a>	

**Patient ID Number:** Will auto-populate and does not need to be entered.

**Is the patient being randomized?**

- If no, you will be prompted to provide reason.
- If yes, the following will auto-populate, based on the responses you entered on the **Enrollment And Eligibility Assessments** and **Demographics** forms:

**The following must be all green in order to meet randomizing criteria:**

Patient hospitalized for >= 24 hours or over a change in calendar date: Yes

Patient hospitalized with: Worsening of chronic heart failure or new diagnosis of heart failure

Plan for a daily outpatient oral loop diuretic regimen upon hospital discharge: Yes

Does the patient have end-stage renal disease requiring renal replacement therapy?: No

Does the patient have a history of heart transplant or actively listed for heart transplant?: No

Does the patient have an implanted LVAD or implant anticipated < 3 months?: No

Is the patient pregnant or nursing?: No

Does the patient have a malignancy or other non-cardiac condition limiting life expectancy to < 12 months?: No

Does the patient have a known hypersensitivity of furosemide, torsemide or related medications?: No

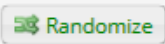
Age >= 18 at time of informed consent: dob - 07-09-1969 informed consent date - 07-02-2018 14:39

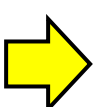
**At least one of the following must be green in addition to all above in order to meet randomizing criteria:**

Left Ventricular Ejection Fraction, % <= 40 : 35

Highest NT-proBNP > upper reference level for current hospitalization: NT-proBNP(\_\_\_\_) and Upper reference level(\_\_\_\_)

Highest BNP > upper reference level for current hospitalization: BNP(\_\_\_\_) and Upper reference level(\_\_\_\_)

Randomized treatment arm 



**Randomization treatment arm: The *Randomize* button will only appear if all rows in the first section are green and at least one row in the second section is green.**

After the randomization button is pressed, the allocated treatment arm will appear on the screen, as shown below, with a note saying "Already randomized". You cannot delete or change the randomization status once the treatment arm has been assigned. **Please save this form after randomizing the patient.**

<b>Randomized treatment arm</b>	Already randomized
	<input type="radio"/> Oral Furosemide <input checked="" type="radio"/> Oral Torsemide

## Study Drug Administration

Complete this form at Gen. Baseline, Rand, & Post.

<b>Was the first dose of study drug administered prior to discharge?</b>	<input type="radio"/> Yes <input type="radio"/> No	reset
--	---	-------

### Was the first dose of study drug administered prior to discharge?

- If no, you will be prompted to provide reason.
- If yes, you will be prompted to provide the following:

<b>Date (time) of first dose after randomization</b>	<input type="text" value="07-16-2019 10:31"/> <input type="button" value="Now"/> M-D-Y H:M <small>mm/dd/yyyy hh:mm</small>	reset
<b>Medication name</b>	<input type="radio"/> Furosemide (oral) <input type="radio"/> Torsemide (oral)	reset
<b>Total daily dose <u>prescribed</u>, mg</b>	<input type="text"/> <small>ex. patient prescribed 20mg, 2x day = 40mg</small>	reset

**Total daily dose prescribed:** Enter actual **total daily dose** prescribed post-randomization in mg; not just the amount administered in the single, first dose.

## Current Hospitalization And Other Information

Complete this form at Gen. Baseline, Rand, & Post.

<b>Date of admission</b>	<input type="text"/> <input type="button" value="Today"/> M-D-Y mm/dd/yyyy
<b>Date of discharge</b>	<input type="text"/> <input type="button" value="Today"/> M-D-Y mm/dd/yyyy
<b>Primary inpatient care team at the time of randomization (i.e., not consult services):</b>	<p><input type="radio"/> Cardiology (e.g., heart failure service, general cardiology service, other cardiology service)</p> <p><input type="radio"/> Hospitalist, internal medicine, or family medicine</p> <p><input type="radio"/> Surgery (e.g., cardiothoracic surgery service, other surgical service)</p> <p><input type="radio"/> Other</p> <p style="text-align: right;"><a href="#">reset</a></p>
<b>Insurance Payors</b>	<p><input type="checkbox"/> Private Health Insurance</p> <p><input type="checkbox"/> Medicare</p> <p><input type="checkbox"/> Medicaid</p> <p><input type="checkbox"/> Military Health Care</p> <p><input type="checkbox"/> State-specific Plan (non-Medicaid)</p> <p><input type="checkbox"/> Indian Health Services</p> <p><input type="checkbox"/> Other US Insurance</p> <p><input type="checkbox"/> None/Self Pay</p> <p><input type="checkbox"/> <a href="#">check all that apply</a></p>

**Date of discharge:** If participant death occurs post randomization and prior to hospital discharge, please report the date of death as the date of discharge.

**Primary inpatient care team at the time of randomization (i.e., not consult services):** Please select the primary inpatient care team at the time of randomization that is not a consult service.

**Insurance Payors:** Check all that apply.

**NDI search information**

**Middle Initial**



Please provide MI. If the participant does not have a middle initial, please write "none". If the middle initial is not known by the site team, please write "UNK". If the participant has multiple middle names, provide the multiple middle initials.

**What is the patient's current marital status?**




- Married or living as married
- Divorced
- Separated
- Widowed
- Never married/Annulled/Single
- Prefers not to answer

[reset](#)

**Middle Initial:** Please provide MI. If the participant does not have a middle initial, please write "none". If the middle initial is not known by the site team, please write "UNK". If the participant has multiple middle names, provide the multiple middle initials.

## Hf Characteristics

Complete this form at Gen. Baseline, Rand, & Post.

<b>Does the patient have a history of HF prior to current hospitalization?</b>	<input type="radio"/> Yes  <input type="radio"/> No	reset
<b>What is the patient's primary HF etiology?</b>	<input type="radio"/> Ischemic <input type="radio"/> Non-ischemic <input type="radio"/> UNK	reset
<b>NYHA class at current hospital admission</b>	<input type="radio"/> I <input type="radio"/> II <input type="radio"/> III <input type="radio"/> IV <input type="radio"/> UNK	reset
<b>NYHA class at time of randomization (or most recent prior to randomization)</b>	<input type="radio"/> I <input type="radio"/> II <input type="radio"/> III <input type="radio"/> IV <input type="radio"/> UNK	reset

**Does the patient have a history of HF prior to current hospitalization?** If yes, you will be prompted to provide the following:

<b>Duration of HF diagnosis prior to current hospitalization</b>	<input type="radio"/> <= 30 days Duration <input type="radio"/> >30 days and <=12 months Duration <input type="radio"/> >12 months Duration <input type="radio"/> UNK	reset
<b>Was the patient hospitalized for HF within 12 months prior to current hospitalization?</b>	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> UNK	reset

## General Medical History

Complete this form at Gen. Baseline, Rand, & Post.

You will be prompted to select Yes/No for the following medical diagnoses:

Does the patient have a medical history of any of the following?	
Atrial fibrillation or atrial flutter	<input type="radio"/> Yes <input type="radio"/> No
Diabetes mellitus	<input type="radio"/> Yes <input type="radio"/> No
Chronic kidney disease	<input type="radio"/> Yes <input type="radio"/> No
Hypertension	<input type="radio"/> Yes <input type="radio"/> No
Hypercholesterolemia	<input type="radio"/> Yes <input type="radio"/> No
Peripheral Artery Disease	<input type="radio"/> Yes <input type="radio"/> No
Coronary Artery Disease	<input type="radio"/> Yes <input type="radio"/> No
Myocardial infarction	<input type="radio"/> Yes <input type="radio"/> No
Prior PCI	<input type="radio"/> Yes <input type="radio"/> No
Prior CABG	<input type="radio"/> Yes <input type="radio"/> No
Chronic lung disease (including COPD)	<input type="radio"/> Yes <input type="radio"/> No
Stroke / TIA	<input type="radio"/> Yes <input type="radio"/> No

**Cigarette smoking**

- Current smoker  
 Former smoker  
 Never smoked

[reset](#)

**Does the patient have any of the following devices currently implanted?**

**Implantable cardioverter defibrillator (ICD)**

- Yes  
 No

[reset](#)

**Cardiac resynchronization therapy (CRT)**

- Yes  
 No

[reset](#)

## Loop Diuretic Use

Complete this form at Gen. Baseline, Rand, & Post.

The first section of the Loop Diuretic Use CRF asks about **oral loop diuretics prior** to the hospitalization.

**Loop diuretic use PRIOR to current hospitalization**

Was the patient actively prescribed an oral loop diuretic prior to current hospital admission?

Yes  No

reset

**Was the patient actively prescribed an oral loop diuretic prior to current hospital admission?** If yes, you will be prompted to provide the following:

**Most recent oral loop diuretic prescribed**

furosemide (Lasix)  
 torsemide (Demadex)  
 bumetanide (Bumex)  
 ethacrynic acid (Edecrin)

reset

**Total daily dose prescribed, mg**

reset

As Needed (PRN)

reset

**Most recent oral loop diuretic prescribed:** Select the diuretic the patient was on prior to (i.e., at the time of) the current hospital admission.

**Total daily dose prescribed:** Enter in mg. Entry should be the patient’s current prescribed dose at the time of admission rather than the typical or average dose that they take.

By convention, if patients take a different dose of STANDING loop diuretic on different days of the week (e.g., furosemide 40 mg M/W/F, none on T/Th), please enter the maximal total daily dose prescribed for any given day. If patients are prescribed an AS NEEDED (i.e., “prn”) loop diuretic prescription, please check the “As Needed (PRN)” checkbox on the form.

Examples:

- furosemide 40 mg M/W/F, none on T/Th = record 40 mg as total daily dose
- No standing furosemide prescription, furosemide 20 mg daily as needed = record 20 mg as total daily dose and select the As Needed (PRN) checkbox
- furosemide 40 mg daily, extra 20 mg daily for worsening symptoms = record 40 mg as total daily dose

The second section of the Loop Diuretic Use CRF asks about **IV loop diuretics during** the hospitalization.

**Loop diuretic use DURING current hospitalization**

Did the patient receive IV loop diuretic during current hospitalization prior to randomization?

- Yes  
 No

reset

**Did the patient receive IV loop diuretic during current hospitalization prior to randomization?** If yes, you will be prompted to provide the following:

What is the most recent IV loop diuretic the patient received prior to randomization?

- furosemide (Lasix)  
 torsemide (Demadex)  
 bumetanide (Bumex)  
 ethacrynic acid (Edecrin)

reset

Maximum daily dose received, mg

**What is the most recent IV loop diuretic the patient received prior to randomization:** Select the IV diuretic received closest to randomization.

**Maximum daily dose received:** Enter the maximum dose (within a 24-hour day) in mg.

## Baseline Medications

Complete this form at Gen. Baseline, Rand, & Post. See *addendum 1* for medication category examples.

Is the patient currently taking any of the following medications at the time of randomization?	
Angiotensin converting enzyme (ACE) inhibitor	<input type="radio"/> Yes <input type="radio"/> No
Angiotensin receptor blocker (ARB)	<input type="radio"/> Yes <input type="radio"/> No
Angiotensin receptor-neprilysin inhibitor (ARNi)	<input type="radio"/> sacubitril/valsartan [Entresto]
Aldosterone antagonists / Mineralocorticoid receptor antagonist (MRA) (e.g., spironolactone, eplerenone)	<input type="radio"/> Yes <input type="radio"/> No
Beta blocker	<input type="radio"/> Yes <input type="radio"/> No
Long-acting nitrate	<input type="radio"/> Yes <input type="radio"/> No
Thiazide diuretics	<input type="radio"/> Yes <input type="radio"/> No
Intravenous inotrope / vasopressor	<input type="radio"/> Yes <input type="radio"/> No
Oral Anticoagulant	<input type="radio"/> Yes <input type="radio"/> No
Other heart failure medications	<input type="checkbox"/> digoxin [Lanoxin, Digox] <input type="checkbox"/> hydralazine [Apresoline] <input type="checkbox"/> ivabradine [Corlanor]
Retired question: Other heart failure medications	<input type="radio"/> digoxin [Lanoxin, Digox] <input type="radio"/> hydralazine [Apresoline] <input type="radio"/> ivabradine [Corlanor]
SGLT-2 inhibitor (e.g., canagliflozin, dapagliflozin, empagliflozin)	<input type="radio"/> Yes <input type="radio"/> No

Respond YES to these questions if any of the listed medication categories listed above are actively prescribed for the patient at the time of randomization. If YES is checked a medication list may appear then select the specific medication that is prescribed.

**Intravenous inotrope / vasopressor:** If yes, check all that apply.

**Oral Anticoagulant:** This is for **oral** anticoagulants only. Answer YES if the patient has taken oral anticoagulants, then check all that apply.

**Other heart failure medications:** Check all that apply.

<b>Other heart failure medications</b>	<input type="checkbox"/> digoxin [Lanoxin, Digox] <input type="checkbox"/> hydralazine [Apresoline] <input type="checkbox"/> ivabradine [Corlanor]
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**Other medications:** Check all that apply.

<b>Other medications</b>	<input type="checkbox"/> GLP-1 agonist <input type="checkbox"/> Oral glucose lowering therapy excluding SGLT-2 inhibitor and GLP-1 agonist <input type="checkbox"/> Insulin therapy <input type="checkbox"/> Aspirin <input type="checkbox"/> Other antiplatelet agent excluding aspirin [examples: Clopidogrel, Ticagrelor, Prasugrel] <input type="checkbox"/> Antiarrhythmic [not including beta-blockers] <input type="checkbox"/> Statin <input type="checkbox"/> Non-statin lipid lowering therapy
--------------------------	---

**If the patient is on a combination medication, please specify both parts.** For isosorbide dinitrate/hydralazine (BiDil), for example, check “isosorbide dinitrate” under *Long-acting nitrate* and “hydralazine” under *Other heart failure medications*.

## Discharge Disposition

Complete this form at Gen. Baseline, Rand, & Post.

Status information at discharge	
<b>What is the patient's disposition at discharge?</b>	<p><input type="radio"/> Home</p> <p><input type="radio"/> Hospice - Home</p> <p><input type="radio"/> Hospice - Health Care Facility</p> <p><input type="radio"/> Acute Care Facility</p> <p><input type="radio"/> Skilled Nursing Facility</p> <p><input type="radio"/> Inpatient Rehabilitation Facility</p> <p><input type="radio"/> Long Term Care Hospital</p> <p><input type="radio"/> Intermediate Care Facility</p> <p><input type="radio"/> Other institution not listed above</p> <p><input type="radio"/> Died in hospital prior to discharge</p> <p><input type="radio"/> Left Against Medical Advice</p>
	<a href="#">reset</a>

### What is the patient's disposition at discharge:

A patient who transfers to another hospital for ongoing medical care should be considered discharge to "Acute Care Facility". However, if the patient is discharged to the other hospital for purposes of rehab, the subject should be considered discharge to "Inpatient Rehabilitation Facility". If the patient is being discharged, please treat the time of transfer as their discharge and document the information in the CRF as you would for a discharge. Please provide the discharge summary at transfer or transfer summary in lieu of discharge summary.

If a *Facility* disposition is chosen, you will be prompted to provide the following:

Discharge institution	
<b>Name</b>	<input type="text"/>
<b>City</b>	<input type="text"/>
<b>State</b>	<input type="text"/>

If *Died in hospital prior to discharge* is chosen, you will be prompted to enter the date of death:

<b>Date of Death</b>	
<b>Date of death</b>	<input type="text"/> <input type="button" value="Today"/> M-D-Y <small>mm/dd/yyyy</small>

## Administrative Fields

Complete this form at [Administrative Forms](#).

<b>Date the informed consent was sent to the Call Center</b>	<input type="text"/> <input type="button" value="Today"/> M-D-Y <small>mm/dd/yyyy</small>
<b>Date the medical release was sent to the Call Center</b>	<input type="text"/> <input type="button" value="Today"/> M-D-Y <small>mm/dd/yyyy</small>
<b>Date the patient contact form was sent to the Call Center</b>	<input type="text"/> <input type="button" value="Today"/> M-D-Y <small>mm/dd/yyyy</small>
<b>Date the discharge instructions were sent to the Call Center</b>	<input type="text"/> <input type="button" value="Today"/> M-D-Y <small>mm/dd/yyyy</small>
<b>What was the patient's study status at discharge?</b>	<input type="radio"/> Continuing in study with full participation <input type="radio"/> Continuing in study with reduced level of participation <input type="radio"/> Withdrew consent for all follow-up

[reset](#)

### What was the patient's study status at discharge?

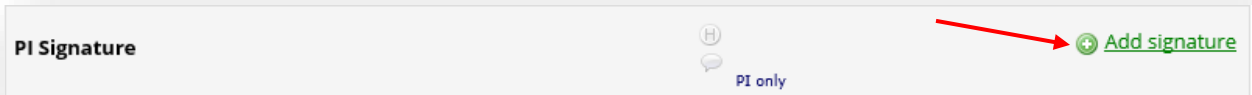
If the participant died while inpatient and the participant had not requested reduce participation or withdrew consent prior to their death, please respond as "continuing in study with full participation"  
 If *Continuing in study with reduced level of participation* is chosen, then you will be prompted to indicate contact level as follows:

<b>For reduced level of participation, please indicate contact level</b>	<input type="radio"/> Reduced call schedule (only call at 12 months) <input type="radio"/> Do not call - medical record follow-up only
--	---

[reset](#)

## PI Signature

Complete this form at [Administrative Forms](#). (Only accessible by PI, should only be completed at end of study)



**PI Signature:** To sign the casebook, click on the [Add signature](#) hyperlink, use the mouse to trace your signature, and then click on the Save signature button.



To complete the PI Signature process, the PI will save the signature form and lock all forms across the subject by clicking the "Lock all instruments" option on the menu at the left.



**Addendum 1**  
**Medication Category Examples**

Angiotensin converting enzyme (ACE) inhibitor	benazepril [Lotensin] captopril [Capoten] enalapril [Epaned, Vasotec, Renitec] fosinopril [Monopril] lisinopril [Prinivil, Zestril] moexipril [Univasc] perindopril [Aceon] quinapril [Accupril] ramipril [Altace] trandolapril [Mavik] other ACE inhibitor
Angiotensin receptor blocker (ARB)	candesartan [Atacand] eprosartan [Teveten] irbesartan [Avapro] losartan [Cozaar] olmesartan [Benicar] telmisartan [Micardis] valsartan [Diovan] other ARB
Angiotensin receptor-neprilysin inhibitor (ARNi)	sacubitril/valsartan [Entresto]
Aldosterone antagonists / Mineralocorticoid receptor antagonist (MRA)	eplerenone [Inspra] spironolactone [Aldactone] other MRA
Beta blocker	acebutolol [Sectral] atenolol [Senormin, Tenormin] betaxolol bisoprolol [Zebeta] carvedilol [Coreg] labetalol [Trandate] metoprolol succinate [Toprol XL] metoprolol tartrate [Lopressor] nadolol [Corgard] nebivolol [Bystolic] penbutolol [Levatol] pindolol [Visken] propranolol [Inderal, Innopran] other beta blocker
Long-acting nitrate	isosorbide dinitrate [dilatrate-SR, isordil, isordil titradose, isosrbid dinitrate]

	isosorbide mononitrate [imdur, ismo, monoket] other long-acting nitrate
Thiazide diuretics	chlorothiazide [Diuril] chlorthalidone [Thalitone] hydrochlorothiazide [Microzide] indapamide metolazone [Zaroxolyn] other thiazide diuretics
Intravenous inotrope / vasopressor	Dobutamine Dopamine Milrinone Other inotrope/vasopressor
Anticoagulant	warfarin (Coumadin) direct oral anticoagulant [examples: Rivaroxaban, Apixaban, Edoxaban, Dabigatran]
Other heart failure medications	digoxin [Lanoxin, Digox] hydralazine [Apresoline] ivabradine [Corlanor]
SGLT-2 inhibitor	canagliflozin [Invokana] dapagliflozin [Farxiga] empagliflozin [Jardiance] Other SGLT-2 inhibitor