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## **SUPPLEMENTARY MATERIAL**

### **Box 1. Conceptualized Modular Case Report Form Additions and Example Data Items**

Arrhythmia Details – cardiac resynchronization therapy and defibrillator device details, anti-arrhythmic agent details and doses

Echocardiogram Details – typical echocardiographic core lab assessments

Electrocardiogram Details –PR interval, ventricular arrhythmia details, bradycardia details

Expanded Cardiovascular Medication Details – doses of vasodilators, digoxin, ivabradine

Expanded Congenital Heart Disease Assessment

Expanded Demographics – gender at enrollment, expanded racial groups

Expanded Event Classification – mortality adjudication including sudden cardiac death, hospitalization adjudication including cardiovascular hospitalization, separation of worsening heart failure equivalents including emergency room visits, observation stays, diuretic infusion clinics, and renal failure events

Expanded Laboratory Details – extended testing including hepatic, glycemic, nutritional, lipid, and inflammatory testing, troponins

Expanded Physical Examination and Vital Signs – temperature, pulmonary examination, abdominal examination

Expanded Surgical and Procedural History Details – radiofrequency ablation, coronary artery bypass grafting, percutaneous coronary intervention, valvular repair or replacement

Genomics Evaluation

Magnetic Resonance Details – typical magnetic resonance imaging core lab assessments

Mechanical Circulatory Support – use of inotropes, intra-aortic balloon pump, ventricular assist devices, extracorporeal membrane oxygenation

Medication Details for Thrombosis – doses of antiplatelet and anticoagulant medications

Medication Details for Antihyperglycemia – doses of antihyperglycemic medications

Metabolic Profiling – inclusive of waist circumference, metabolomic profiling, biomarkers

Objective Functional Assessment – 6-minute walk test, cardiopulmonary exercise test, gait speed, frailty, physical performance battery

Quality of Life Subscales and Expanded Quality of Life Assessments

Expanded Endpoint Ascertainment – mortality subsets, hospitalization subsets, heart failure hospitalization equivalents, patient reported outcome assessments

## **Box 2. Included Medical History Elements**

### Cardiovascular Medical History

Hospitalization for HF with in the prior 12 months, or equivalent (IV diuretics)

Predominant etiology of HF

Prior myocardial infarction

Prior coronary revascularization (surgical or percutaneous)

Presence of moderate or severe valvular regurgitation (any cardiac valve)

Presence of moderate or severe valvular stenosis (any cardiac valve)

Current use of another medical device (pacemaker, ICD, CRT, CPAP, phrenic nerve stimulator, oxygen therapy)

Presence of hypertension

Presence of atrial Fibrillation or flutter

Presence of ventricular tachycardia or fibrillation

Presence of cerebrovascular disease

Presence of peripheral vascular disease

### Non-Cardiovascular Medical History

History of diabetes mellitus

History of smoking

History of chronic obstructive pulmonary disease

History of sleep apnea

History of depression

History of dyslipidemia

History of cancer requiring chemotherapy or radiation

History of renal dysfunction (with Chronic Kidney Disease Stage by estimated glomerular filtration rate)

## Appendix A. Participants in the Lean CRF Working Group

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## Appendix B. Consensus Adult Case Report Form for Devices

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### DEMOGRAPHICS

1. Birth Month \_\_\_\_ and Birth Year \_\_\_\_

2. Sex at Birth:

Male

Female

3. Ethnicity:

Hispanic or Latino

Not Hispanic or Latino

Not Reported or Refused

4. Race as determined by patient or family (Check all that apply)

American Indian, First Nations, or Aboriginal

Alaska Native

Black or African American

Asian Indian

Chinese

Filipino

Japanese

- Korean
- Vietnamese
- Other Asian
- Native Hawaiian
- Pacific Islander (Other than Native Hawaiian)
- White or Caucasian
- Not Reported or Refused

#### PHYSICAL EXAMINATION

5. Height \_\_\_\_\_  cm  in
6. Weight \_\_\_\_\_  kg  lb
7. Resting Heart Rate: \_\_\_\_\_ (beats/min)
8. Resting Systolic Blood Pressure: \_\_\_\_\_ (mmHg)
9. Resting Diastolic Blood Pressure: \_\_\_\_\_ (mmHg)
10. Resting Respiratory Rate: \_\_\_\_\_ (respirations/min)
  
11. HF Assessment: (Dichotomous yes/no)

Peripheral Edema -  yes  no

Rales/Rhonchi -  yes  no

Jugular Venous Distention (JVD) -  yes  no

S3 gallop -  yes  no

#### CARDIAC ASSESSMENT



12. Left Ventricular Ejection Fraction Assessment: (Within \_\_\_\_ months)

13. Left Ventricular Ejection Fraction: (Single number, range not allowed) \_\_\_\_\_ %

14. Left Ventricular Ejection Fraction Modality:

Echocardiogram

Magnetic Resonance Imaging

Gated myocardial perfusion imaging; single photon emission computed tomography (SPECT)  
or positron emission tomography (PET)

Gated Equilibrium Radionuclide Ventriculography (MUGA)

Left ventricular contrast ventriculography during invasive catheterization

15. Electrocardiogram: (Within \_\_\_\_ months)

Sinus rhythm

Atrial Fibrillation/Flutter

Ventricular Paced

Ventricular rate \_\_\_\_\_ beats/min

QRS Duration \_\_\_\_\_ milliseconds

Left Bundle Branch Block present

16. NYHA Class at time of consent

I

II

III

IV

## PATIENT REPORTED OUTCOMES ASSESSMENT

17. Patient-Reported Outcome by Qualified Medical Device Development Tool at time of Enrollment:

O KCCQ (Kansas City Cardiomyopathy Questionnaire) Overall Summary Score \_\_\_\_\_

O MLHFQ (Minnesota Living with HF Questionnaire) Total Score \_\_\_\_\_

## CARDIOVASCULAR MEDICAL HISTORY

18. Hospitalization due to Heart Failure (or equivalent) within prior 12 months? O yes O no

19. Predominant Ischemic Etiology of Heart Failure - O yes O no

20. Coronary Artery Disease:

Previous Myocardial Infarction - O yes O no

Previous Revascularization (Coronary Artery Bypass or Percutaneous Coronary Intervention) - O yes O no

21. Known Moderate or Severe Valvular Regurgitation (check all that apply)

O Aortic

O Mitral

O Tricuspid

O Pulmonic

O None

22. Known Moderate or Severe Valvular Stenosis (check all that apply)

- Aortic
- Mitral
- Tricuspid
- Pulmonic
- None

23. Medical Devices (Check all that apply)

- Pacemaker (non-CRT, non-ICD)
- Implantable Cardioverter-Defibrillator (ICD; non-CRT)
- Cardiac Resynchronization Therapy (CRT-P, non-ICD)
- Cardiac Resynchronization Therapy, Implantable Cardioverter-Defibrillator (CRT-D)
- Continuous Positive Airway Pressure (CPAP)
- Phrenic Nerve Stimulator
- Continuous Oxygen Therapy
- Durable Left Ventricular Assist Device
- Other
- None

24. History of Hypertension -  yes  no

25. History of Atrial fibrillation/flutter -  yes  no

26. History of Ventricular tachycardia/fibrillation -  yes  no

27. History of Cerebrovascular Disease -  yes  no

28. History of Peripheral Vascular Disease -  yes  no

#### NON-CARDIOVASCULAR MEDICAL HISTORY

29. History of Diabetes Mellitus -  None  Type 1  Type 2  Unknown Type

30. Smoking Status -  Current  Former  Never

31. History of COPD -  yes  no

32. History of Sleep Apnea -  yes  no

33. History of Depression -  yes  no

34. History of Dyslipidemia -  yes  no

35. History of Cancer Requiring Chemotherapy or Radiation -  yes  no

36. Renal Function at Enrollment by Estimated Glomerular Filtration Rate (eGFR; Chronic  
Kidney Disease Stage)

I (eGFR  $\geq 90$  ml/min/1.73m<sup>2</sup>)

II (eGFR 60-89 ml/min/1.73m<sup>2</sup>)

IIIa (eGFR 45-59 ml/min/1.73m<sup>2</sup>)

IIIb (eGFR 30-44 ml/min/1.73m<sup>2</sup>)

IV (eGFR 15-29 ml/min/1.73m<sup>2</sup>)

V (eGFR  $< 15$  ml/min/1.73m<sup>2</sup>)

#### BASELINE LABORATORY VALUES

37. Serum Hemoglobin \_\_\_\_  g/dL  mmol/l

38. Serum Sodium \_\_\_\_  mEq/l  mmol/l

39. Serum Potassium \_\_\_\_ O mEq/l O mmol/l
40. Blood Urea Nitrogen \_\_\_\_ O mg/dL O mmol/l
41. Serum Creatinine \_\_\_\_ O mg/dL O mmol/l
42. Natriuretic Peptides \_\_\_\_ O BNP O NT-proBNP (pg/ml)
43. Serum Glucose \_\_\_\_ O mEq/l O mmol/l

#### BASELINE MEDICATIONS

44. Loop Diuretics (total daily dose, select all that apply)

- Furosemide \_\_\_\_ mg
- Torsemide \_\_\_\_ mg
- Bumetanide \_\_\_\_ mg
- Ethacrynic Acid \_\_\_\_ mg
- None

45. Thiazide Diuretics (total daily dose, select all that apply)

- Hydrochlorothiazide \_\_\_\_ mg
- Chlorthalidone \_\_\_\_ mg
- Chlorothiazide \_\_\_\_ mg
- Indapamide \_\_\_\_ mg
- Metolazone \_\_\_\_ mg
- Methyclothiazide \_\_\_\_ mg
- None

46. Mineralocorticoid Receptor Antagonists (total daily dose, select all that apply)

- Spironolactone \_\_\_\_ mg
- Eplerenone \_\_\_\_ mg
- Canrenone \_\_\_\_ mg
- None

47. Renin-Angiotensin System Inhibitors (total daily dose, select all that apply)

- Benazepril \_\_\_\_ mg
- Captopril \_\_\_\_ mg
- Enalapril \_\_\_\_ mg
- Fosinopril \_\_\_\_ mg
- Lisinopril \_\_\_\_ mg
- Moexipril \_\_\_\_ mg
- Perindopril \_\_\_\_ mg
- Quinapril \_\_\_\_ mg
- Ramipril \_\_\_\_ mg
- Trandolapril \_\_\_\_ mg
- Azilsartan \_\_\_\_ mg
- Candesartan \_\_\_\_ mg
- Eprosartan \_\_\_\_ mg
- Irbesartan \_\_\_\_ mg
- Losartan \_\_\_\_ mg
- Olmesartan \_\_\_\_ mg

- O Telmisartan \_\_\_\_ mg
- O Valsartan \_\_\_\_ mg
- O Sacubitril-Valsartan \_\_\_\_ mg
- O Aliskiren \_\_\_\_ mg
- O None

48. Beta-Adrenergic Receptor Blockers (total daily dose, select all that apply)

- O Acebutolol \_\_\_\_ mg
- O Atenolol \_\_\_\_ mg
- O Betaxolol \_\_\_\_ mg
- O Bisoprolol \_\_\_\_ mg
- O Bucindolol \_\_\_\_ mg
- O Carvedilol \_\_\_\_ mg
- O Labetalol \_\_\_\_ mg
- O Metoprolol tartrate \_\_\_\_ mg
- O Metoprolol succinate \_\_\_\_ mg
- O Nadolol \_\_\_\_ mg
- O Nebivolol \_\_\_\_ mg
- O Penbutolol \_\_\_\_ mg
- O Pindolol \_\_\_\_ mg
- O Propranolol \_\_\_\_ mg
- O None

#### OTHER HF MEDICATIONS

- 49. Digoxin  yes  no
- 50. Ivabradine  yes  no
- 51. Tolvaptan  yes  no
- 52. Hydralazine  yes  no
- 53. Isosorbide-Mononitrate  yes  no
- 54. Isosorbide-Dinitrate  yes  no

#### OTHER CARDIOVASCULAR MEDICATIONS

- 55. Any Antiarrhythmic Medication  yes  no
- 56. Any Calcium Channel Antagonist  yes  no
- 57. Aspirin  yes  no
- 58. Any Non-Aspirin Anti-Platelet Agent  yes  no
- 59. Warfarin  yes  no
- 60. Any Direct Oral Anti-Coagulant  yes  no
- 61. Any Statin  yes  no
- 62. Any Additional Anti-Hypertensive Medication  yes  no

#### ANTI-HYPERGLYCEMIC MEDICATIONS

- 63. Metformin  yes  no
- 64. Any Sulfonylurea  yes  no
- 65. Any Thiazolidinedione  yes  no
- 66. Any Glucagon-Like Peptide-1 (GLP-1) Antagonist  yes  no



67. Any Dipeptidyl-peptidase-4 (DPP-4) Antagonist  yes  no

68. Any Sodium-Glucose Co-Transporter-2 (SGLT-2) Antagonist  yes  no

69. Any Insulin  yes  no

#### HEART FAILURE MEDICAL AND DEVICE THERAPY EXPLANATION

70. Renin-Angiotensin System Inhibitor at goal dose  yes  no

71. If Renin-Angiotensin System Inhibitor not at goal dose, this is due to (select all that apply):

Hyperkalemia

Renal Dysfunction

Hypotension

Bradycardia

Other Side Effect or Intolerance

Physician Decision-Making other than Side Effects or Intolerance

72. Beta-Adrenergic Receptor Blocker at goal dose  yes  no

73. If Beta-Adrenergic Receptor Blocker not at goal dose, this is due to (select all that apply):

Hyperkalemia

Renal Dysfunction

Hypotension

Bradycardia

Other Side Effect or Intolerance

Physician Decision-Making other than Side Effects or Intolerance

74. Mineralocorticoid Receptor Antagonist at goal dose  yes  no

75. If Mineralocorticoid Receptor Antagonist not at goal dose, this is due to (select all that apply):

Hyperkalemia

Renal Dysfunction

Hypotension

Bradycardia

Other Side Effect or Intolerance

Physician Decision-Making other than Side Effects or Intolerance

#### EVENTS

1. All-Cause Mortality \_\_\_\_\_ (date)

2. Cardiovascular Mortality  yes  no

3. Left Ventricular Assist Device (LVAD) or Heart Transplant \_\_\_\_\_ (date)

4. All-Cause Hospitalization \_\_\_\_\_ (date)

5. Heart Failure Hospitalization  yes  no

6. Other Worsening Heart Failure Event Requiring Intravenous Diuretic \_\_\_\_\_ (date)

(Emergency Department, Observation Visit, Clinic Visit, or Other Intravenous Diuretic

Administration)

7. Patient-Reported Outcome by Qualified Medical Device Development Tool:

KCCQ (Kansas City Cardiomyopathy Questionnaire) Overall Summary Score \_\_\_\_\_

MLHFQ (Minnesota Living with Heart Failure Questionnaire) Total Score \_\_\_\_\_



## **Appendix C. Consensus Adult Case Report Form for Drugs**

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Preamble: The Consensus Adult Lean Case Report Form for Drugs is intended to apply to most standard clinical trials of new drugs for the treatment of heart failure to be used for regulatory approval. Limitation of the data items collected may be reasonable in direct consultation with the United States Food and Drug Administration.

The lean case report form for drugs is distinct from the case report form for devices in the following ways:

Includes: assessment of the symptoms needed for the diagnosis of heart failure and whether heart failure was previously diagnosed.

Does not include: assessment of the modality used to determine left ventricular ejection fraction (LVEF) or baseline laboratory values.

### DEMOGRAPHICS

1. Birth Month \_\_\_\_ and Birth Year \_\_\_\_

2. Sex at Birth:

Male

Female

3. Ethnicity:

Hispanic or Latino

Not Hispanic or Latino

Not Reported or Refused

4. Race as determined by patient or family (Check all that apply)

American Indian, First Nations, or Aboriginal

Alaska Native

Black or African American

Asian Indian

Chinese

Filipino

Japanese

Korean

Vietnamese

Other Asian

Native Hawaiian

Pacific Islander (Other than Native Hawaiian)

White or Caucasian

Not Reported or Refused

#### PHYSICAL EXAMINATION

5. Height \_\_\_\_\_  cm  in

6. Weight \_\_\_\_\_  kg  lb

7. Resting Heart Rate: \_\_\_\_\_ (beats/min)

8. Resting Systolic Blood Pressure: \_\_\_\_\_ (mmHg)

9. Resting Diastolic Blood Pressure: \_\_\_\_\_ (mmHg)

10. Resting Respiratory Rate: \_\_\_\_\_ (respirations/min)

11. Symptom Report: (Patient Reported Dichotomous yes/no)

Edema -  yes  no

Dyspnea -  yes  no

Orthopnea -  yes  no

Fatigue -  yes  no

12. Heart Failure Assessment: (Clinician Assessed Dichotomous yes/no)

Peripheral Edema -  yes  no

Rales/Rhonchi -  yes  no

Jugular Venous Distention (JVD) -  yes  no

S3 gallop -  yes  no

#### CARDIAC ASSESSMENT

13. Left Ventricular Ejection Fraction Assessment: (Within \_\_\_\_\_ months)

14. Left Ventricular Ejection Fraction: (Single number, range not allowed) \_\_\_\_\_ %

15. Electrocardiographic Assessment proximal to Enrollment

Sinus rhythm or  Atrial Fibrillation/Atrial Flutter or  Atrial Paced

QRS Duration \_\_\_\_\_ milliseconds

Left Bundle Branch Block present

16. NYHA Class at time of consent

I

II

III

IV

#### CARDIOVASCULAR MEDICAL HISTORY

17. Prior diagnosis of heart failure -  yes  no

18. Hospitalization due to heart failure (or equivalent) within the prior 12 months -  yes  no

19. Predominant ischemic etiology of heart failure -  yes  no

20. Known Coronary Artery Disease -  yes  no

21. Previous Myocardial Infarction -  yes  no

22. Previous Revascularization (Coronary Artery Bypass or Percutaneous Coronary Intervention)  
-  yes  no

23. Known Moderate or Severe Valvular Regurgitation (check all that apply)

Aortic

Mitral

Tricuspid

Pulmonic

None

24. Known Moderate or Severe Valvular Stenosis (check all that apply)

Aortic

Mitral

Tricuspid

Pulmonic

None

25. Medical Devices (Check all that apply)

Pacemaker (non-CRT, non-ICD)

Implantable Cardioverter-Defibrillator (ICD; non-CRT)

Cardiac Resynchronization Therapy (CRT-P, non-ICD)

Cardiac Resynchronization Therapy, Implantable Cardioverter-Defibrillator (CRT-D)

Continuous Positive Airway Pressure (CPAP)

Phrenic Nerve Stimulator

Continuous Oxygen Therapy

Durable Left Ventricular Assist Device

Other

None

26. History of Hypertension -  yes  no

27. History of Atrial fibrillation/flutter -  yes  no



28. History of Ventricular tachycardia/fibrillation -  yes  no

29. History of Cerebrovascular Disease -  yes  no

30. History of Peripheral Vascular Disease -  yes  no

31. History of Congenital Heart Disease:  yes  no

#### NON-CARDIOVASCULAR MEDICAL HISTORY

32. History of Diabetes Mellitus -  None  Type 1  Type 2  Unknown Type

33. Smoking Status -  Current  Former  Never

34. History of COPD -  yes  no

35. History of Sleep Apnea -  yes  no

36. History of Depression -  yes  no

37. History of Dyslipidemia -  yes  no

38. History of Cancer Requiring Chemotherapy or Radiation -  yes  no

39. Renal Function at Enrollment by Estimated Glomerular Filtration Rate (eGFR) and Chronic  
Kidney Disease Stage

I (GFR  $\geq$ 90 ml/min/1.73m<sup>2</sup>)

II (GFR 60-89 ml/min/1.73m<sup>2</sup>)

IIIa (GFR 45-59 ml/min/1.73m<sup>2</sup>)

IIIb (GFR 30-44 ml/min/1.73m<sup>2</sup>)

IV (GFR 15-29 ml/min/1.73m<sup>2</sup>)

V (GFR <15 ml/min/1.73m<sup>2</sup>)

40. Current treatment with Dialysis -  yes  no

#### BASELINE MEDICATIONS

41. Loop Diuretics (total daily dose, select all that apply)

Furosemide \_\_\_\_ mg

Torsemide \_\_\_\_ mg

Bumetanide \_\_\_\_ mg

Ethacrynic Acid \_\_\_\_ mg

None

42. Thiazide Diuretic  yes  no

43. Mineralocorticoid Receptor Antagonists (total daily dose, select all that apply)

Spironolactone \_\_\_\_ mg

Eplerenone \_\_\_\_ mg

Canrenone \_\_\_\_ mg

None

44. Renin-Angiotensin System Inhibitors (total daily dose, select all that apply)

Benazepril \_\_\_\_ mg

Captopril \_\_\_\_ mg

Enalapril \_\_\_\_ mg

Fosinopril \_\_\_\_ mg

- Lisinopril \_\_\_\_ mg
- Moexipril \_\_\_\_ mg
- Perindopril \_\_\_\_ mg
- Quinapril \_\_\_\_ mg
- Ramipril \_\_\_\_ mg
- Trandolapril \_\_\_\_ mg
- Azilsartan \_\_\_\_ mg
- Candesartan \_\_\_\_ mg
- Eprosartan \_\_\_\_ mg
- Irbesartan \_\_\_\_ mg
- Losartan \_\_\_\_ mg
- Olmesartan \_\_\_\_ mg
- Telmisartan \_\_\_\_ mg
- Valsartan \_\_\_\_ mg
- Sacubitril-Valsartan \_\_\_\_ mg
- Aliskiren \_\_\_\_ mg
- None

45. Beta-Adrenergic Receptor Blockers (total daily dose, select all that apply)

- Acebutolol \_\_\_\_ mg
- Atenolol \_\_\_\_ mg
- Betaxolol \_\_\_\_ mg
- Bisoprolol \_\_\_\_ mg

O Bucindolol \_\_\_\_ mg

O Carvedilol \_\_\_\_ mg

O Labetalol \_\_\_\_ mg

O Metoprolol tartrate \_\_\_\_ mg

O Metoprolol succinate \_\_\_\_ mg

O Nadolol \_\_\_\_ mg

O Nebivolol \_\_\_\_ mg

O Penbutolol \_\_\_\_ mg

O Pindolol \_\_\_\_ mg

O Propranolol \_\_\_\_ mg

O None

#### OTHER HF MEDICATIONS

46. Digoxin O yes O no

47. Ivabradine O yes O no

48. Tolvaptan O yes O no

49. Hydralazine O yes O no

50. Isosorbide-Mononitrate O yes O no

51. Isosorbide-Dinitrate O yes O no

#### OTHER CARDIOVASCULAR MEDICATIONS

52. Any Antiarrhythmic Medication O yes O no

53. Any Calcium Channel Antagonist O yes O no

54. Aspirin  yes  no

55. Any Non-Aspirin Anti-Platelet Agent  yes  no

56. Warfarin  yes  no

57. Any Direct Oral Anti-Coagulant  yes  no

58. Any Statin  yes  no

59. Any Additional Anti-Hypertensive Medication  yes  no

#### ANTI-HYPERGLYCEMIC MEDICATIONS

60. Metformin  yes  no

61. Any Sulfonylurea  yes  no

62. Any Thiazolidinedione  yes  no

63. Any Glucagon-Like Peptide-1 (GLP-1) Agonist  yes  no

64. Any Dipeptidyl-peptidase-4 (DPP-4) Antagonist  yes  no

65. Any Sodium-Glucose Co-Transporter-2 (SGLT-2) Antagonist  yes  no

66. Any Insulin  yes  no

#### HF MEDICAL THERAPY EXPLANATION

67. If no Renin-Angiotensin System Inhibitor, this is due to (select all that apply):

Hyperkalemia

Renal Dysfunction

Hypotension

Bradycardia

Other Side Effect or Intolerance

Physician Decision-Making other than Side Effects or Intolerance (including lack of indication)

68. If no Beta-Adrenergic Receptor Blocker, this is due to (select all that apply):

Hyperkalemia

Renal Dysfunction

Hypotension

Bradycardia

Other Side Effect or Intolerance

Physician Decision-Making other than Side Effects or Intolerance (including lack of indication)

69. If no Mineralocorticoid Receptor Antagonist, this is due to (select all that apply):

Hyperkalemia

Renal Dysfunction

Hypotension

Bradycardia

Other Side Effect or Intolerance

Physician Decision-Making other than Side Effects or Intolerance (including lack of indication)

## EVENTS

8. All-Cause Mortality \_\_\_\_\_ (date)

9. Cardiovascular Mortality  yes  no  unknown

10. All-Cause Hospitalization \_\_\_\_\_ (date)

11. Cardiovascular Hospitalization  yes  no  unknown

12. Heart Failure Hospitalization  yes  no  unknown