**Consensus Adult Case Report Form for Devices**

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DEMOGRAPHICS

1. Birth Month \_\_\_\_ and Birth Year \_\_\_\_
2. Sex at Birth:

O Male

O Female

1. Ethnicity:

О Hispanic or Latino

О Not Hispanic or Latino

О Not Reported or Refused

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

O American Indian, First Nations, or Aboriginal

O Alaska Native

O Black or African American

O Asian Indian

O Chinese

O Filipino

O Japanese

O Korean

O Vietnamese

O Other Asian

O Native Hawaiian

O Pacific Islander (Other than Native Hawaiian)

O White or Caucasian

O Not Reported or Refused

PHYSICAL EXAMINATION

1. Height \_\_\_\_\_\_\_\_ О cm О in
2. Weight \_\_\_\_\_\_\_\_ О kg О lb
3. Resting Heart Rate: \_\_\_\_\_\_\_\_\_\_ (beats/min)
4. Resting Systolic Blood Pressure: \_\_\_\_\_\_\_\_\_\_ (mmHg)
5. Resting Diastolic Blood Pressure: \_\_\_\_\_\_\_\_\_ (mmHg)
6. Resting Respiratory Rate: \_\_\_\_\_\_\_ (respirations/min)
7. HF Assessment: (Dichotomous yes/no)

Peripheral Edema - О yes О no

Rales/Rhonchi - О yes О no

Jugular Venous Distention (JVD) - О yes О no

S3 gallop - О yes О no

Ascites or Abdominal Distension - О yes О no

Hepatojugular reflux - О yes О no

CARDIAC ASSESSMENT

1. Left Ventricular Ejection Fraction Assessment: (Within \_\_\_\_ months)
2. Left Ventricular Ejection Fraction: (Single number, range not allowed) \_\_\_\_\_ %
3. Left Ventricular Ejection Fraction Modality:

О Echocardiogram

О Magnetic Resonance Imaging

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

О Gated Equilibrium Radionucleotide Ventriculography (MUGA)

О Left ventricular contrast ventriculography during invasive catheterization

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

О Sinus rhythm

О Atrial Fibrillation/Flutter

О Ventricular Paced

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

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

О Left Bundle Branch Block present

1. NYHA Class at time of consent

О I

О II

О III

О IV

PATIENT REPORTED OUTCOMES ASSESSMENT

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

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

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

CARDIOVASCULAR MEDICAL HISTORY

1. Hospitalization due to Heart Failure (or equivalent) within prior 12 months? О yes О no
2. Predominant Ischemic Etiology of Heart Failure - О yes О no
3. Coronary Artery Disease:

Previous Myocardial Infarction - О yes О no

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

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

О Aortic

О Mitral

О Tricuspid

О Pulmonic

О None

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

О Aortic

О Mitral

О Tricuspid

О Pulmonic

О None

1. Medical Devices (Check all that apply)

О Pacemaker (non-CRT, non-ICD)

О Implantable Cardioverter-Defibrillator (ICD; non-CRT)

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

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

О Leadless Pacemaker

О Subcutaneous Defibrillator

О Continuous Positive Airway Pressure (CPAP)

О Phrenic Nerve Stimulator

О Continuous Oxygen Therapy

О Durable Left Ventricular Assist Device

О Other

О None

1. History of Hypertension - О yes О no
2. History of Atrial fibrillation/flutter - О yes О no
3. History of Ventricular tachycardia/fibrillation - О yes О no
4. History of Cerebrovascular Disease - О yes О no
5. History of Peripheral Vascular Disease - О yes О no

NON-CARDIOVASCULAR MEDICAL HISTORY

1. History of Diabetes Mellitus - О None О Type 1 О Type 2 О Unknown Type
2. Smoking Status - О Current О Former О Never
3. History of COPD - О yes О no
4. History of Sleep Apnea - О yes О no
5. History of Depression - О yes О no
6. History of Dyslipidemia - О yes О no
7. History of Cancer Requiring Chemotherapy or Radiation - О yes О no
8. Renal Function at Enrollment by Estimated Glomerular Filtration Rate (eGFR; Chronic Kidney Disease Stage)

О I (eGFR ≥90 ml/min/1.73m2)

О II (eGFR 60-89 ml/min/1.73m2)

О IIIa (eGFR 45-59 ml/min/1.73m2)

О IIIb (eGFR 30-44 ml/min/1.73m2)

О IV (eGFR 15-29 ml/min/1.73m2)

О V (eGFR <15 ml/min/1.73m2)

BASELINE LABORATORY VALUES

1. Serum Hemoglobin \_\_\_\_ О g/dL О mmol/l
2. Serum Sodium \_\_\_\_ О mEq/l О mmol/l
3. Serum Potassium \_\_\_\_ О mEq/l О mmol/l
4. Blood Urea Nitrogen \_\_\_\_ О mg/dL О mmol/l
5. Serum Creatinine \_\_\_\_ О mg/dL О mmol/l
6. Natriuretic Peptides \_\_\_\_ О BNP О NT-proBNP (pg/ml)
7. Serum Glucose \_\_\_\_ О mEq/l О mmol/l

BASELINE MEDICATIONS

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

О Furosemide \_\_\_\_ mg

О Torsemide \_\_\_\_ mg

О Bumetanide \_\_\_\_ mg

О Ethacrynic Acid \_\_\_\_ mg

О None

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

О Hydrochlorothiazide \_\_\_\_ mg

О Chlorthalidone \_\_\_\_ mg

О Chlorothiazide \_\_\_\_ mg

О Indapamide \_\_\_\_ mg

О Metolazone \_\_\_\_ mg

О Methyclothiazide \_\_\_\_ mg

О None

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

О Spironolactone \_\_\_\_ mg

О Eplerenone \_\_\_\_ mg

О Canrenone \_\_\_\_ mg

О None

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

О Benazepril \_\_\_\_ mg

О Captopril \_\_\_\_ mg

О Enalapril \_\_\_\_ mg

О Fosinopril \_\_\_\_ mg

О Lisinopril \_\_\_\_ mg

О Moexipril \_\_\_\_ mg

О Perindopril \_\_\_\_ mg

О Quinapril \_\_\_\_ mg

О Ramipril \_\_\_\_ mg

О Trandolapril \_\_\_\_ mg

О Azilsartan \_\_\_\_ mg

О Candesartan \_\_\_\_ mg

О Eprosartan \_\_\_\_ mg

О Irbesartan \_\_\_\_ mg

О Losartan \_\_\_\_ mg

О Olmesartan \_\_\_\_ mg

О Telmisartan \_\_\_\_ mg

О Valsartan \_\_\_\_ mg

О Sacubitril-Valsartan \_\_\_\_ mg

О Aliskiren \_\_\_\_ mg

О None

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

О Acebutolol \_\_\_\_ mg

О Atenolol \_\_\_\_ mg

О Betaxolol \_\_\_\_ mg

О Bisoprolol \_\_\_\_ mg

О Bucindolol \_\_\_\_ mg

О Carvedilol \_\_\_\_ mg

О Labetalol \_\_\_\_ mg

О Metoprolol tartrate \_\_\_\_ mg

О Metoprolol succinate \_\_\_\_ mg

О Nadolol \_\_\_\_ mg

О Nebivolol \_\_\_\_ mg

О Penbutolol \_\_\_\_ mg

О Pindolol \_\_\_\_ mg

О Propranolol \_\_\_\_ mg

О None

1. Sodium-Glucose Co-Transporter-2 (SGLT-2) Antagonist

О Dapagliflozin

О Empagliflozin

О None

OTHER HF MEDICATIONS

1. Digoxin О yes О no
2. Ivabradine О yes О no
3. Tolvaptan О yes О no
4. Hydralazine О yes О no
5. Isosorbide-Mononitrate О yes О no
6. Isosorbide-Dinitrate О yes О no

OTHER CARDIOVASCULAR MEDICATIONS

1. Any Antiarrhythmic Medication О yes О no
2. Any Calcium Channel Antagonist О yes О no
3. Aspirin О yes О no
4. Any Non-Aspirin Anti-Platelet Agent О yes О no
5. Warfarin О yes О no
6. Any Direct Oral Anti-Coagulant О yes О no
7. Any Statin О yes О no
8. Any Additional Anti-Hypertensive Medication О yes О no

ANTI-HYPERGLYCEMIC MEDICATIONS

1. Metformin О yes О no
2. Any Sulfonylurea О yes О no
3. Any Thiazolidinedione О yes О no
4. Any Glucagon-Like Peptide-1 (GLP-1) Antagonist О yes О no
5. Any Dipeptidyl-peptidase-4 (DPP-4) Antagonist О yes О no
6. Any Insulin О yes О no

HEART FAILURE MEDICAL AND DEVICE THERAPY EXPLANATION

1. Renin-Angiotensin System Inhibitor at goal dose О yes О no
2. If Renin-Angiotensin System Inhibitor not at goal dose, this is due to (select all that apply):

О Hyperkalemia

О Renal Dysfunction

О Hypotension

О Bradycardia

О Other Side Effect or Intolerance

О Physician Decision-Making other than Side Effects or Intolerance

1. Beta-Adrenergic Receptor Blocker at goal dose О yes О no
2. If Beta-Adrenergic Receptor Blocker not at goal dose, this is due to (select all that apply):

О Hyperkalemia

О Renal Dysfunction

О Hypotension

О Bradycardia

О Other Side Effect or Intolerance

О Physician Decision-Making other than Side Effects or Intolerance

1. Mineralocorticoid Receptor Antagonist at goal dose О yes О no
2. If Mineralocorticoid Receptor Antagonist not at goal dose, this is due to (select all that apply):

О Hyperkalemia

О Renal Dysfunction

О Hypotension

О Bradycardia

О Other Side Effect or Intolerance

О Physician Decision-Making other than Side Effects or Intolerance

EVENTS

1. All-Cause Mortality \_\_\_\_\_\_\_\_ (date)
2. Cardiovascular Mortality О yes О no
3. Left Ventricular Assist Device (LVAD) or Heart Transplant \_\_\_\_\_\_\_\_ (date)
4. All-Cause Hospitalization \_\_\_\_\_\_\_\_ (date)
5. Heart Failure Hospitalization О yes О no
6. Other Worsening Heart Failure Event Requiring Intravenous Diuretic \_\_\_\_\_\_\_\_ (date)

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

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

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

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

**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:

O Male

O Female

1. Ethnicity:

О Hispanic or Latino

О Not Hispanic or Latino

О Not Reported or Refused

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

O American Indian, First Nations, or Aboriginal

O Alaska Native

O Black or African American

O Asian Indian

O Chinese

O Filipino

O Japanese

O Korean

O Vietnamese

O Other Asian

O Native Hawaiian

O Pacific Islander (Other than Native Hawaiian)

O White or Caucasian

O Not Reported or Refused

PHYSICAL EXAMINATION

1. Height \_\_\_\_\_\_\_\_ О cm О in
2. Weight \_\_\_\_\_\_\_\_ О kg О lb
3. Resting Heart Rate: \_\_\_\_\_\_\_\_\_\_ (beats/min)
4. Resting Systolic Blood Pressure: \_\_\_\_\_\_\_\_\_\_ (mmHg)
5. Resting Diastolic Blood Pressure: \_\_\_\_\_\_\_\_\_ (mmHg)
6. Resting Respiratory Rate: \_\_\_\_\_\_\_ (respirations/min)
7. Symptom Report: (Patient Reported Dichotomous yes/no)

Edema - О yes О no

Dyspnea - О yes О no

Orthopnea - О yes О no

Fatigue - О yes О no

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

Peripheral Edema - О yes О no

Rales/Rhonchi - О yes О no

Jugular Venous Distention (JVD) - О yes О no

S3 gallop - О yes О no

Ascites or Abdominal Distension - О yes О no

Hepatojugular reflux - О yes О no

CARDIAC ASSESSMENT

1. Left Ventricular Ejection Fraction Assessment: (Within \_\_\_\_ months)
2. Left Ventricular Ejection Fraction: (Single number, range not allowed) \_\_\_\_\_ %
3. Electrocardiographic Assessment proximal to Enrollment

О Sinus rhythm or О Atrial Fibrillation/Atrial Flutter or О Atrial Paced

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

О Left Bundle Branch Block present

1. NYHA Class at time of consent

О I

О II

О III

О IV

CARDIOVASCULAR MEDICAL HISTORY

1. Prior diagnosis of heart failure - О yes О no
2. Hospitalization due to heart failure (or equivalent) within the prior 12 months - О yes О no
3. Predominant ischemic etiology of heart failure - О yes О no
4. Known Coronary Artery Disease - О yes О no
5. Previous Myocardial Infarction - О yes О no
6. Previous Revascularization (Coronary Artery Bypass or Percutaneous Coronary Intervention) - О yes О no
7. Known Moderate or Severe Valvular Regurgitation (check all that apply)

О Aortic

О Mitral

О Tricuspid

О Pulmonic

О None

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

О Aortic

О Mitral

О Tricuspid

О Pulmonic

О None

1. Medical Devices (Check all that apply)

О Pacemaker (non-CRT, non-ICD)

О Implantable Cardioverter-Defibrillator (ICD; non-CRT)

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

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

О Leadless Pacemaker

О Subcutaneous Defibrillator

О Continuous Positive Airway Pressure (CPAP)

О Phrenic Nerve Stimulator

О Continuous Oxygen Therapy

О Durable Left Ventricular Assist Device

О Other

О None

1. History of Hypertension - О yes О no
2. History of Atrial fibrillation/flutter - О yes О no
3. History of Ventricular tachycardia/fibrillation - О yes О no
4. History of Cerebrovascular Disease - О yes О no
5. History of Peripheral Vascular Disease - О yes О no
6. History of Congenital Heart Disease: О yes О no

NON-CARDIOVASCULAR MEDICAL HISTORY

1. History of Diabetes Mellitus - О None О Type 1 О Type 2 О Unknown Type
2. Smoking Status - О Current О Former О Never
3. History of COPD - О yes О no
4. History of Sleep Apnea - О yes О no
5. History of Depression - О yes О no
6. History of Dyslipidemia - О yes О no
7. History of Cancer Requiring Chemotherapy or Radiation - О yes О no
8. Renal Function at Enrollment by Estimated Glomerular Filtration Rate (eGFR) and Chronic Kidney Disease Stage

О I (GFR ≥90 ml/min/1.73m2)

О II (GFR 60-89 ml/min/1.73m2)

О IIIa (GFR 45-59 ml/min/1.73m2)

О IIIb (GFR 30-44 ml/min/1.73m2)

О IV (GFR 15-29 ml/min/1.73m2)

О V (GFR <15 ml/min/1.73m2)

1. Current treatment with Dialysis - О yes О no

BASELINE MEDICATIONS

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

О Furosemide \_\_\_\_ mg

О Torsemide \_\_\_\_ mg

О Bumetanide \_\_\_\_ mg

О Ethacrynic Acid \_\_\_\_ mg

О None

1. Thiazide Diuretic О yes О no
2. Mineralocorticoid Receptor Antagonists (total daily dose, select all that apply)

О Spironolactone \_\_\_\_ mg

О Eplerenone \_\_\_\_ mg

О Canrenone \_\_\_\_ mg

О None

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

О Benazepril \_\_\_\_ mg

О Captopril \_\_\_\_ mg

О Enalapril \_\_\_\_ mg

О Fosinopril \_\_\_\_ mg

О Lisinopril \_\_\_\_ mg

О Moexipril \_\_\_\_ mg

О Perindopril \_\_\_\_ mg

О Quinapril \_\_\_\_ mg

О Ramipril \_\_\_\_ mg

О Trandolapril \_\_\_\_ mg

О Azilsartan \_\_\_\_ mg

О Candesartan \_\_\_\_ mg

О Eprosartan \_\_\_\_ mg

О Irbesartan \_\_\_\_ mg

О Losartan \_\_\_\_ mg

О Olmesartan \_\_\_\_ mg

О Telmisartan \_\_\_\_ mg

О Valsartan \_\_\_\_ mg

О Sacubitril-Valsartan \_\_\_\_ mg

О Aliskiren \_\_\_\_ mg

О None

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

О Acebutolol \_\_\_\_ mg

О Atenolol \_\_\_\_ mg

О Betaxolol \_\_\_\_ mg

О Bisoprolol \_\_\_\_ mg

О Bucindolol \_\_\_\_ mg

О Carvedilol \_\_\_\_ mg

О Labetalol \_\_\_\_ mg

О Metoprolol tartrate \_\_\_\_ mg

О Metoprolol succinate \_\_\_\_ mg

О Nadolol \_\_\_\_ mg

О Nebivolol \_\_\_\_ mg

О Penbutolol \_\_\_\_ mg

О Pindolol \_\_\_\_ mg

О Propranolol \_\_\_\_ mg

О None

1. Sodium-Glucose Co-Transporter-2 (SGLT-2) Antagonist

О Dapagliflozin

О Empagliflozin

О None

OTHER HF MEDICATIONS

1. Digoxin О yes О no
2. Ivabradine О yes О no
3. Tolvaptan О yes О no
4. Hydralazine О yes О no
5. Isosorbide-Mononitrate О yes О no
6. Isosorbide-Dinitrate О yes О no

OTHER CARDIOVASCULAR MEDICATIONS

1. Any Antiarrhythmic Medication О yes О no
2. Any Calcium Channel Antagonist О yes О no
3. Aspirin О yes О no
4. Any Non-Aspirin Anti-Platelet Agent О yes О no
5. Warfarin О yes О no
6. Any Direct Oral Anti-Coagulant О yes О no
7. Any Statin О yes О no
8. Any Additional Anti-Hypertensive Medication О yes О no

ANTI-HYPERGLYCEMIC MEDICATIONS

1. Metformin О yes О no
2. Any Sulfonylurea О yes О no
3. Any Thiazolidinedione О yes О no
4. Any Glucagon-Like Peptide-1 (GLP-1) Agonist О yes О no
5. Any Dipeptidyl-peptidase-4 (DPP-4) Antagonist О yes О no
6. Any Insulin О yes О no

HF MEDICAL THERAPY EXPLANATION

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

О Hyperkalemia

О Renal Dysfunction

О Hypotension

О Bradycardia

О Other Side Effect or Intolerance

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

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

О Hyperkalemia

О Renal Dysfunction

О Hypotension

О Bradycardia

О Other Side Effect or Intolerance

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

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

О Hyperkalemia

О Renal Dysfunction

О Hypotension

О Bradycardia

О Other Side Effect or Intolerance

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

EVENTS

1. All-Cause Mortality \_\_\_\_\_\_\_\_ (date)
2. Cardiovascular Mortality О yes О no О unknown
3. All-Cause Hospitalization \_\_\_\_\_\_\_\_ (date)
4. Cardiovascular Hospitalization О yes О no О unknown
5. Heart Failure Hospitalization О yes О no О unknown