**ACUTE DECOMPENSATED HEART FAILURE & CARDIOGENIC SHOCK: CRF MODULES\***

Preamble: The Consensus Adult Lean Case Report Form is intended to apply to most standard clinical trials of new drugs and devices for the treatment of acute decompensated heart failure and cardiogenic shock 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. If the inclusion/exclusion criteria eliminates an element, it does not need to be included.

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| **DEMOGRAPHICS**  Birth Month \_\_\_\_ and Birth Year \_\_\_\_  Sex at Birth:  O Male  O Female    Ethnicity:  О Hispanic or Latino  О Not Hispanic or Latino  О Not Reported or Refused  Race as determined by patient or family (Check all that apply)  O American Indian or Alaska Native  O Asian  O Black or African American  O Native Hawaiian or Pacific Islander  O White  O Not Reported or Refused | Ethnicity/Race categories taken from FDA guidance document on collection of Race and Ethnicity Data in Clinical Trials (https://www.fda.gov/media/75453/download) |
| **CARDIOVASCULAR MEDICAL HISTORY**  Prior diagnosis of heart failure - О yes О no  Hospitalization due to heart failure (or equivalent) within the prior 12 months –  О yes \_\_\_\_\_\_\_\_Date О no  Previous Myocardial Infarction - О yes О no  Previous Revascularization (Coronary Artery Bypass or Percutaneous Coronary Intervention) - О yes О no  Known Moderate or Severe Valvular Regurgitation (check all that apply)  О Aortic  О Mitral  О Tricuspid  О Pulmonic  О None  Known Moderate or Severe Valvular Stenosis (check all that apply)  О Aortic  О Mitral  О Tricuspid  О Pulmonic  О None  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 Continuous Oxygen Therapy  О Durable Left Ventricular Assist Device  О Other  О None  History of Hypertension - О yes О no  History of Atrial fibrillation/flutter - О yes О no  History of Ventricular tachycardia/fibrillation - О yes О no  History of Cerebrovascular Disease - О yes О no  History of Peripheral Vascular Disease - О yes О no  History of Congenital Heart Disease: О yes О no  **NON-CARDIOVASCULAR MEDICAL HISTORY**  History of Diabetes Mellitus - О None О Type 1 О Type 2 О Unknown Type  Smoking Status - О Current О Former О Never  History of COPD - О yes О no  History of Sleep Apnea - О yes О no  History of Depression - О yes О no  History of Dyslipidemia - О yes О no  History of Cancer Requiring Chemotherapy or Radiation - О yes О no  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)  Current treatment with Dialysis - О yes О no |  |
| **BASELINE PHYSICAL EXAMINATION**  Height \_\_\_\_\_\_\_\_ О cm О in  Weight \_\_\_\_\_\_\_\_ О kg О lb  Resting Heart Rate: \_\_\_\_\_\_\_\_\_\_ (beats/min)  Resting Systolic Blood Pressure: \_\_\_\_\_\_\_\_\_\_(mmHg)  Resting Diastolic Blood Pressure: \_\_\_\_\_\_\_\_\_ (mmHg)  Resting Respiratory Rate: \_\_\_\_\_\_\_ (respirations/min) |  |
| **HF SIGNS & SYMPTOMS**  Heart Failure Assessment: (Clinician Assessed Dichotomous yes/no)  Peripheral Edema - О yes О no  Rales - О yes О no  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  NYHA Class at time of consent  О I  О II  О III  О IV  SCAI Stage  О A  О B  О C  О D  О E  Symptom Report: (Patient Reported Dichotomous yes/no)  Orthopnea О yes О no  Fatigue - О yes О no | Trials can choose which elements they want to document to highlight severity of ADHF  See Also:   1. Hemodynamics Module (https://hfcollaboratory.com/wp-content/uploads/2021/12/LeanCRF\_Hemodynamics\_12\_13\_2021.pdf) |
| **CARDIAC ASSESSMENT**   1. Left Ventricular Ejection Fraction Assessment: (Date\_\_\_\_) 2. Left Ventricular Ejection Fraction: (Single number, range not allowed) \_\_\_\_\_ % 3. LVEF 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. Electrocardiographic (Date\_\_\_\_)   О Sinus Rhythm or О Atrial Fibrillation/Atrial Flutter or О Atrial Paced or  О Ventricular Paced  Ventricular Rate \_\_\_ beats/min  QRS Duration \_\_\_\_\_ milliseconds  О Left Bundle Branch Block present | See Also:   1. Echocardiography Module (<https://hfcollaboratory.com/wp-content/uploads/2021/08/HFC-LeanCRF_Echocardiography-Module-19-JUL-2021.docx>) 2. MRI Module (https://hfcollaboratory.com/wp-content/uploads/2021/08/HFC-Lean-CRF-Cardiac-Magnetic-Resonance-Imaging-MRI-Module-19-JUL-2021.docx) 3. Electrocardiographic Details Module (https://hfcollaboratory.com/wp-content/uploads/2021/03/ElectrocradiogramModule\_FINAL\_2\_2021.docx) |
| **ENROLLMENT 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) | See Also:   1. Expanded Laboratory Details (https://hfcollaboratory.com/wp-content/uploads/2021/06/LeanCRF\_LabDetails\_final.docx) |
| **FOLLOW-UP 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) | Frequency to be determined by trialists  See Also:   1. Expanded Laboratory Details (https://hfcollaboratory.com/wp-content/uploads/2021/06/LeanCRF\_LabDetails\_final.docx) |
| **AT ENROLLMENT PRO ASSESSMENT**  Patient-Reported Outcome by Qualified Medical Device Development Tool at time of Enrollment (select all that apply:  О KCCQ (Kansas City Cardiomyopathy Questionnaire) Overall Summary Score \_\_\_\_\_\_\_\_\_  О MLHFQ (Minnesota Living with HF Questionnaire) Total Score \_\_\_\_\_\_\_\_\_  О Patient Global Assessment Score \_\_\_\_\_\_ |  |
| **AT ENROLLMENT MEDICATIONS/THERAPIES**  Loop Diuretics (total daily dose, select all that apply)  О Furosemide \_\_\_\_ mg  О Torsemide \_\_\_\_ mg  О Bumetanide \_\_\_\_ mg  О Ethacrynic Acid \_\_\_\_ mg  Acetazolamide  О None  Thiazide Diuretic О yes О no  О None  Combination of diuretics О yes О no  **GUIDELINE DIRECTED MEDICAL THERAPY**  Mineralocorticoid Receptor Antagonists (total daily dose, select all that apply)  О Spironolactone \_\_\_\_ mg  О Eplerenone \_\_\_\_ mg  О Canrenone \_\_\_\_ mg  О Finerenone\_\_\_\_ mg  О None  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  Beta-Adrenergic Receptor Blockers (total daily dose, select all that apply)  О Bisoprolol \_\_\_\_ mg  О Carvedilol \_\_\_\_ mg  О Metoprolol succinate \_\_\_\_ mg  О None  Sodium-Glucose Co-Transporter-2 (SGLT-2) Antagonist  О Dapagliflozin  О Empagliflozin  О Sotagliflozin  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   **ADHF-SPECIFIC THERAPIES** *(primarily for U.S. Sites)*  **VASOACTIVE AGENTS**  О Norepinephrine  О Epinephrine  О Dopamine  О Dobutamine  О Milrinone  О Vasopressin  О Sodium nitroprusside  О Phenylephrine  О Levosimendan  О None  **MCS DEVICES**  О IABP  О temporary/durable LVAD  О ECMO  О TAH  О None  **MECHANICAL FLUID REMOVAL**  О Ultrafiltration  О Hemofiltration  О Thoracentesis  О Paracentesis  О None | Can be tailored to the study whether or not diuretic dose needs to be specified.  Maybe since it’s a combo product?  Should we specify – “include any/all therapies instituted at any time during index hospitalization”  See Also:   1. Short term MCS Module(https://hfcollaboratory.com/wp-content/uploads/2021/10/HFCLeanCRF\_Short-termMCS.docx) 2. Durable MCS Module (https://hfcollaboratory.com/wp-content/uploads/2021/06/LeanCRF\_LabDetails\_final.docx) |
| **FOLLOW UP TREATMENT ASSESSMENT**  Loop Diuretics (total daily dose, select all that apply)  О Furosemide \_\_\_\_ mg  О Torsemide \_\_\_\_ mg  О Bumetanide \_\_\_\_ mg  О Ethacrynic Acid \_\_\_\_ mg  Acetazolamide  О None  Thiazide Diuretic О yes О no  О None  Combination of diuretics О yes О no  **GUIDELINE DIRECTED MEDICAL THERAPY**  Mineralocorticoid Receptor Antagonists (total daily dose, select all that apply)  О Spironolactone \_\_\_\_ mg  О Eplerenone \_\_\_\_ mg  О Canrenone \_\_\_\_ mg  О Finerenone\_\_\_\_ mg  О None  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  Beta-Adrenergic Receptor Blockers (total daily dose, select all that apply)  О Bisoprolol \_\_\_\_ mg  О Carvedilol \_\_\_\_ mg  О Metoprolol succinate \_\_\_\_ mg  О None  Sodium-Glucose Co-Transporter-2 (SGLT-2) Antagonist  О Dapagliflozin  О Empagliflozin  О Sotagliflozin  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   **ADHF-SPECIFIC THERAPIES** *(primarily for U.S. Sites)*  **VASOACTIVE AGENTS**  О Norepinephrine  О Epinephrine  О Dopamine  О Dobutamine  О Milrinone  О Vasopressin  О Sodium nitroprusside  О Phenylephrine  О Levosimendan  О None  **MCS DEVICES**  О IABP  О temporary/durable LVAD  О ECMO  О TAH  О None  **MECHANICAL FLUID REMOVAL**  О Ultrafiltration  О Hemofiltration  О Thoracentesis  О Paracentesis  О None | Frequency to be determined by trialists |
| **SUGGESTED EVENTS TO COLLECT**   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 \_\_\_\_\_\_\_\_ (date) 5. Heart Failure Hospitalization О yes О no О unknown \_\_\_\_\_\_\_\_ (date) 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 \_\_\_\_\_\_\_\_\_  **ADHF-SPECIFIC ENDPOINTS**   1. Date of Admission 2. Date of Discharge 3. Date of ICU Transfer/Admission 4. Date of ICU Discharge | \*If multiple hospitalizations, record each hospitalization date, and etiology of hospitalization (ie. all-cause, cardiovascular, heart failure)  See J Am Coll Cardiol HF 2023;xx:xx-xx) |

\*Includes CRF elements from HFC Lean Case Report Form for Chronic Heart Failure (https://hfcollaboratory.com/wp-content/uploads/2021/03/Lean-CRF-UpdateFeb25\_2021.docx)