**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 MaleO Female Ethnicity:О Hispanic or LatinoО Not Hispanic or Latino О Not Reported or RefusedRace as determined by patient or family (Check all that apply)O American Indian or Alaska NativeO 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 noHospitalization due to heart failure (or equivalent) within the prior 12 months – О yes \_\_\_\_\_\_\_\_Date О noPrevious Myocardial Infarction - О yes О noPrevious Revascularization (Coronary Artery Bypass or Percutaneous Coronary Intervention) - О yes О noKnown Moderate or Severe Valvular Regurgitation (check all that apply)О AorticО MitralО TricuspidО PulmonicО NoneKnown Moderate or Severe Valvular Stenosis (check all that apply)О AorticО MitralО TricuspidО PulmonicО NoneMedical 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 TherapyО Durable Left Ventricular Assist DeviceО OtherО NoneHistory of Hypertension - О yes О noHistory of Atrial fibrillation/flutter - О yes О noHistory of Ventricular tachycardia/fibrillation - О yes О noHistory of Cerebrovascular Disease - О yes О noHistory of Peripheral Vascular Disease - О yes О noHistory 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 TypeSmoking Status - О Current О Former О NeverHistory of COPD - О yes О noHistory of Sleep Apnea - О yes О noHistory of Depression - О yes О noHistory of Dyslipidemia - О yes О noHistory of Cancer Requiring Chemotherapy or Radiation - О yes О noRenal Function at Enrollment by Estimated Glomerular Filtration Rate (eGFR) and Chronic Kidney Disease StageО 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 inWeight \_\_\_\_\_\_\_\_ О kg О lbResting 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 noRales - О yes О noJVD - О yes О noS3 gallop - О yes О noAscites or Abdominal Distension - О yes О noHepatojugular reflux - О yes О noNYHA Class at time of consentО IО IIО IIIО IVSCAI StageО AО BО CО DО ESymptom Report: (Patient Reported Dichotomous yes/no)Orthopnea О yes О noFatigue - О yes О no | Trials can choose which elements they want to document to highlight severity of ADHFSee Also:1. Hemodynamics Module (https://hfcollaboratory.com/wp-content/uploads/2021/12/LeanCRF\_Hemodynamics\_12\_13\_2021.pdf)
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| **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 catheterization1. Electrocardiographic (Date\_\_\_\_)

О Sinus Rhythm or О Atrial Fibrillation/Atrial Flutter or О Atrial Paced or О Ventricular PacedVentricular Rate \_\_\_ beats/minQRS Duration \_\_\_\_\_ millisecondsО 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)
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| **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)
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| **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 trialistsSee Also:1. Expanded Laboratory Details (https://hfcollaboratory.com/wp-content/uploads/2021/06/LeanCRF\_LabDetails\_final.docx)
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| **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 \_\_\_\_ mgО Torsemide \_\_\_\_ mgО Bumetanide \_\_\_\_ mgО Ethacrynic Acid \_\_\_\_ mg AcetazolamideО NoneThiazide Diuretic О yes О noО NoneCombination 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 NoneRenin-Angiotensin System Inhibitors (total daily dose, select all that apply)О Benazepril \_\_\_\_ mgО Captopril \_\_\_\_ mgО Enalapril \_\_\_\_ mgО Fosinopril \_\_\_\_ mgО Lisinopril \_\_\_\_ mgО Moexipril \_\_\_\_ mgО Perindopril \_\_\_\_ mgО Quinapril \_\_\_\_ mgО Ramipril \_\_\_\_ mgО Trandolapril \_\_\_\_ mgО Azilsartan \_\_\_\_ mgО Candesartan \_\_\_\_ mgО Eprosartan \_\_\_\_ mgО Irbesartan \_\_\_\_ mgО Losartan \_\_\_\_ mgО Olmesartan \_\_\_\_ mgО Telmisartan \_\_\_\_ mgО Valsartan \_\_\_\_ mgО Sacubitril-Valsartan \_\_\_\_/\_\_\_mgО Aliskiren \_\_\_\_ mgО NoneBeta-Adrenergic Receptor Blockers (total daily dose, select all that apply) О Bisoprolol \_\_\_\_ mg  О Carvedilol \_\_\_\_ mg О Metoprolol succinate \_\_\_\_ mg О NoneSodium-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 NorepinephrineО EpinephrineО DopamineО DobutamineО MilrinoneО VasopressinО Sodium nitroprussideО PhenylephrineО LevosimendanО None**MCS DEVICES**О IABPО temporary/durable LVADО ECMOО TAHО None**MECHANICAL FLUID REMOVAL**О UltrafiltrationО HemofiltrationО ThoracentesisО ParacentesisО 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)
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| **FOLLOW UP TREATMENT ASSESSMENT**Loop Diuretics (total daily dose, select all that apply)О Furosemide \_\_\_\_ mgО Torsemide \_\_\_\_ mgО Bumetanide \_\_\_\_ mgО Ethacrynic Acid \_\_\_\_ mg AcetazolamideО NoneThiazide Diuretic О yes О noО NoneCombination 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 NoneRenin-Angiotensin System Inhibitors (total daily dose, select all that apply)О Benazepril \_\_\_\_ mgО Captopril \_\_\_\_ mgО Enalapril \_\_\_\_ mgО Fosinopril \_\_\_\_ mgО Lisinopril \_\_\_\_ mgО Moexipril \_\_\_\_ mgО Perindopril \_\_\_\_ mgО Quinapril \_\_\_\_ mgО Ramipril \_\_\_\_ mgО Trandolapril \_\_\_\_ mgО Azilsartan \_\_\_\_ mgО Candesartan \_\_\_\_ mgО Eprosartan \_\_\_\_ mgО Irbesartan \_\_\_\_ mgО Losartan \_\_\_\_ mgО Olmesartan \_\_\_\_ mgО Telmisartan \_\_\_\_ mgО Valsartan \_\_\_\_ mgО Sacubitril-Valsartan \_\_\_\_/\_\_\_mg О Aliskiren \_\_\_\_ mgО NoneBeta-Adrenergic Receptor Blockers (total daily dose, select all that apply) О Bisoprolol \_\_\_\_ mg  О Carvedilol \_\_\_\_ mg О Metoprolol succinate \_\_\_\_ mg О NoneSodium-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 NorepinephrineО EpinephrineО DopamineО DobutamineО MilrinoneО VasopressinО Sodium nitroprussideО PhenylephrineО LevosimendanО None**MCS DEVICES**О IABPО temporary/durable LVADО ECMOО TAHО None**MECHANICAL FLUID REMOVAL**О UltrafiltrationО HemofiltrationО ThoracentesisО ParacentesisО 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)