RESPONDER-HF

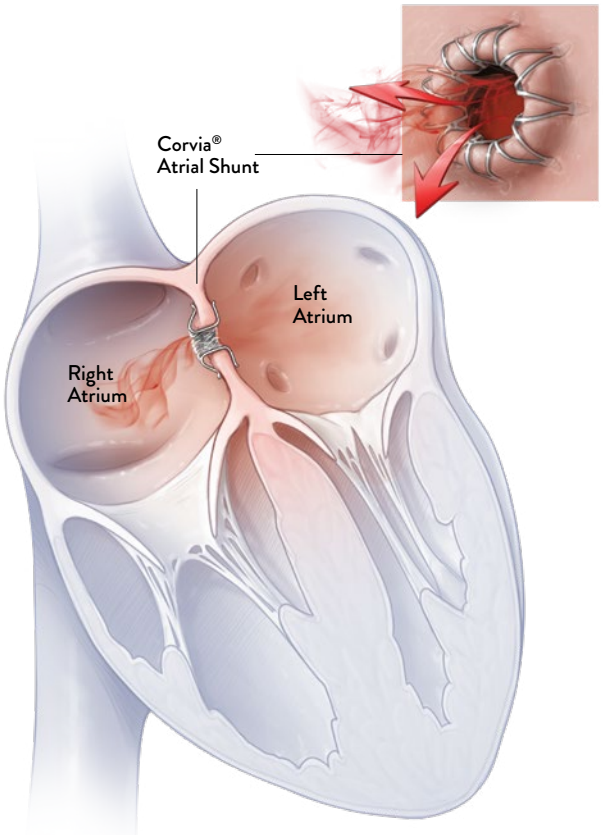
Participant Identification Guide

A clinical trial to confirm the efficacy of atrial shunt therapy in heart failure patients with EF≥40%

corvia®

The RESPONDER-HF trial is being conducted to confirm the clinical efficacy of the **Corvia® Atrial Shunt System** in heart failure (HF) patients with left ventricular ejection fraction (LVEF) ≥40% and elevated left atrial pressure who remain symptomatic despite standard Guideline Directed Medical Therapy (GDMT).

Placed during a catheter-based procedure, the Corvia Atrial Shunt creates a passage between the left and right atria. This passage allows blood to flow from the high pressure left atrium to the lower pressure right atrium, thereby reducing pressure in the left side of the heart and the lungs. By facilitating continuous and dynamic decompression of the left atrium, the Corvia Atrial Shunt has been shown to reduce HF hospitalizations, improve heart failure symptoms and quality of life.



RESPONDER-HF
INCLUSION/EXCLUSION CRITERIA

Key Inclusion Criteria

- Chronic symptomatic HF documented by the following:
  - Symptoms of HF requiring current treatment with diuretics if tolerated for ≥30 days; AND
  - NYHA Class II, III, or ambulatory IV symptoms; AND
  - ≥1 HF hospital admission OR treatment with intravenous (IV) diuretics; or intensification of oral diuresis within the past 12 months; OR an NT-pro BNP value >150 pg/ml in normal sinus rhythm, >450 pg/ml in atrial fibrillation, or a BNP value >50 pg/ml in normal sinus rhythm, >150 pg/ml in atrial fibrillation within the past 6 months
- Ongoing stable GDMT HF management and management of comorbidities according to the 2022 ACC/AHA/HFSA or 2021 ESC Heart Failure Practice Guidelines
- Age ≥ 40 years old
- Echocardiographic LVEF ≥40% within the past 6 months, without documented EF <30% in the prior 5 years
- Elevated exercise PCWP (≥25 mmHg) with left-to-right gradient (≥5 mmHg)
- Peak exercise PVR <1.75 Wood units

Key Exclusion Criteria

- Any implanted cardiac rhythm device
- Presence of hemodynamically significant valve disease
  - Mitral valve disease defined as grade ≥3+ MR or > mild MS; OR
  - Tricuspid valve regurgitation defined as grade ≥2+; OR
  - Aortic valve disease defined as ≥2+ AR or > moderate AS
- Stroke, TIA, DVT or PE within the past 6 months
- Right ventricular dysfunction defined as
  - More than mild RV dysfunction as estimated by TTE; OR
  - TAPSE <1.4 cm
- Currently requiring dialysis; or eGFR <25ml/min/1.73 m^2
- BMI >45

H_2FpEF SCORING MODEL[1]

Created to simplify the identification of HFpEF patients among those with exertional dyspnea.

	Clinical Variable	Values	Points
H_2	**H**eavy	Body mass index > 30 kg/m^2	+2
	Hypertensive	On > 2 anti-hypertensives	+1
F	Atrial **F**ibrillation	Paroxysmal or Persistent AF	+3
P	**P**ulmonary Hypertension	RVSP > 35 mmHg	+1
E	**E**lder	Age > 60 years	+1
F	**F**illing Pressure	E/e' > 9	+1

H_2FPEF Score **Sum (0-9)**

A score of	3	4	5	6+
Indicates a HFpEF probability of	>50%	>70%	>80%	>90%

A score of **4** means
a **>70%** chance of HFpEF

Consider sending high probability HFpEF patients for further evaluation

For more information, please contact:

Place Study Site Principal Investigator Contact Information Here
(Avery 5160 — Label Size 2.625″ x 1″)

1. Reddy YNV, Carter RE, Obokata M, Redfield MM, Borlaug BA. A Simple, Evidence-Based Approach to Help Guide Diagnosis of Heart Failure With Preserved Ejection Fraction. *Circulation*. 2018;138(9):861-870.

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