

# RESPONDER-HF

A confirmatory trial of the Corvia<sup>®</sup> Atrial Shunt for heart failure patients with an EF  $\geq$ 40%



## WHAT IS RESPONDER-HF?

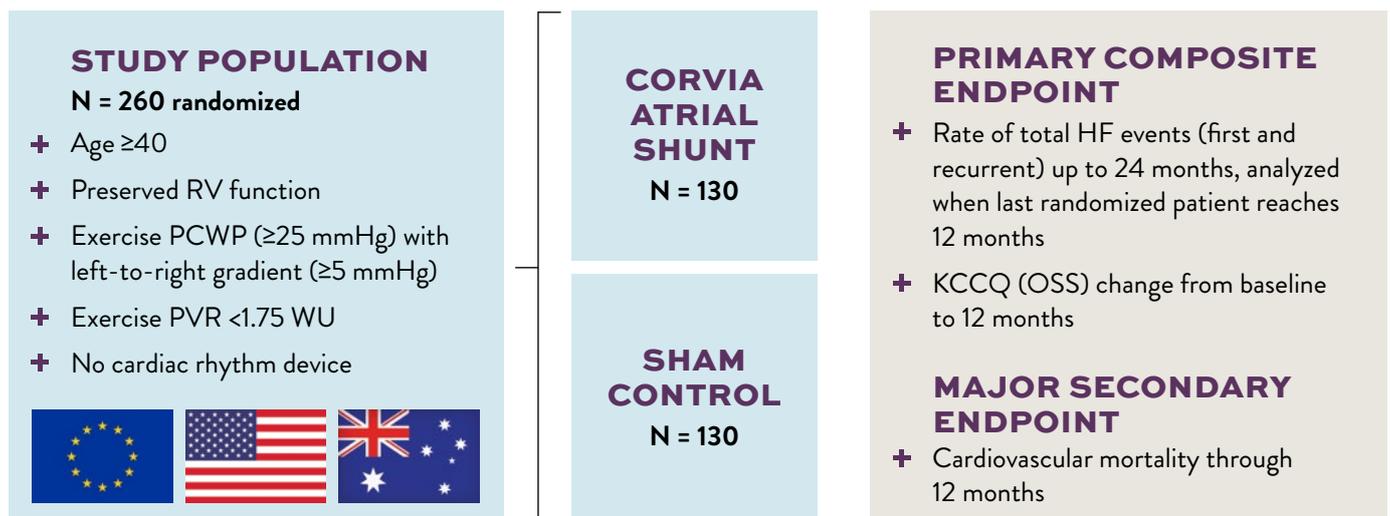
A randomized, double-blinded, sham-controlled trial to confirm the clinical efficacy of the Corvia Atrial Shunt in HF patients with an LVEF  $\geq$ 40%, elevated left sided filling pressures, and who remain symptomatic despite Guideline Directed Medical Therapy (GDMT).

## STUDY RATIONALE

To confirm the findings from REDUCE LAP-HF II, the largest randomized controlled trial of a device-based therapy for HFpEF. Results from REDUCE LAP-HF II showed that in the large responder population, representing 50% of patients, treatment with the Corvia Atrial Shunt resulted in a 45% reduction in HF events ( $p=0.034$ ) and a 55% greater improvement in quality of life compared to sham control at one year ( $p=0.027$ ).<sup>1</sup>

## TRIAL DESIGN

The study closely mirrors REDUCE LAP-HF II, with new exclusions for patients with worse right ventricular function resulting from latent pulmonary vascular disease (identified by elevated exercise PVR) or associated with cardiac rhythm devices.



## WHO SHOULD BE CONSIDERED?

Patients age 40+ who have symptomatic HF or unexplained exertional dyspnea.

- Left ventricular ejection fraction  $\geq$ 40%
- New York Heart Association class II-IV
- Relatively normal right ventricular function
- Elevated left-sided filling pressures
- Absence of significant valve disease
- Absence of a cardiac rhythm device

<sup>1</sup> Borlaug, BA et al.. *Circulation*. 2022;10.1161.

Study sponsored by Corvia Medical. [clinicaltrials.gov/identification/NCT05425459](https://clinicaltrials.gov/identification/NCT05425459)

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Learn more

Consider giving your HFpEF patients a new opportunity to find relief.

**CAUTION:** Investigational Device. Limited by United States law to investigational use.

The Corvia Atrial Shunt System is an Investigational Device, exclusively for use in a Clinical Investigation.

