



## REDUCE LAP-HF II CLINICAL TRIAL SUMMARY



### RESPONDER GROUP HIGHLIGHTS

- + 50% of study patients demonstrated significant clinical benefit (responder group)
- + 45% reduction in heart failure event rate vs. sham control
- + 55% greater improvement in KCCQ vs. sham control at 12 months
- + Exercise phenotyping identified as critical for patient selection

# CORVIA® ATRIAL SHUNT

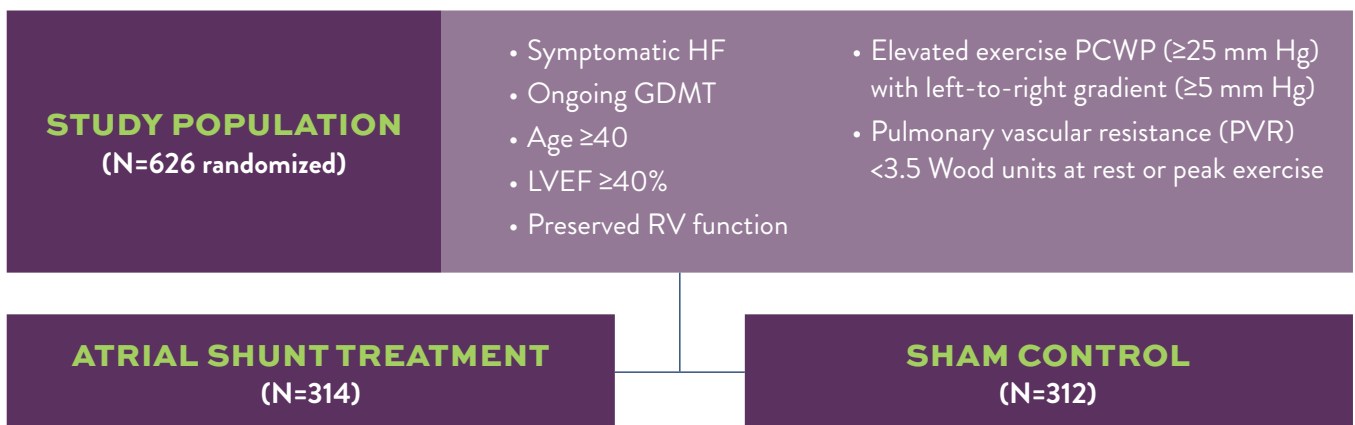


Implanted in over 550 patients worldwide and reviewed in more than 20 publications, the Corvia Atrial Shunt is the world's most clinically and scientifically studied atrial shunt for the reduction of Left Atrial Pressure (LAP) in HFpEF/HFmrEF patients. Results from multiple REDUCE LAP-HF studies have demonstrated the safety and efficacy of the device.

Recently published in *Circulation*, results from REDUCE LAP-HF II, the world's first phase III randomized trial for atrial shunting in heart failure, reinforce the safety and efficacy of the device, and have newly defined the treatable patient population for atrial shunt therapy.

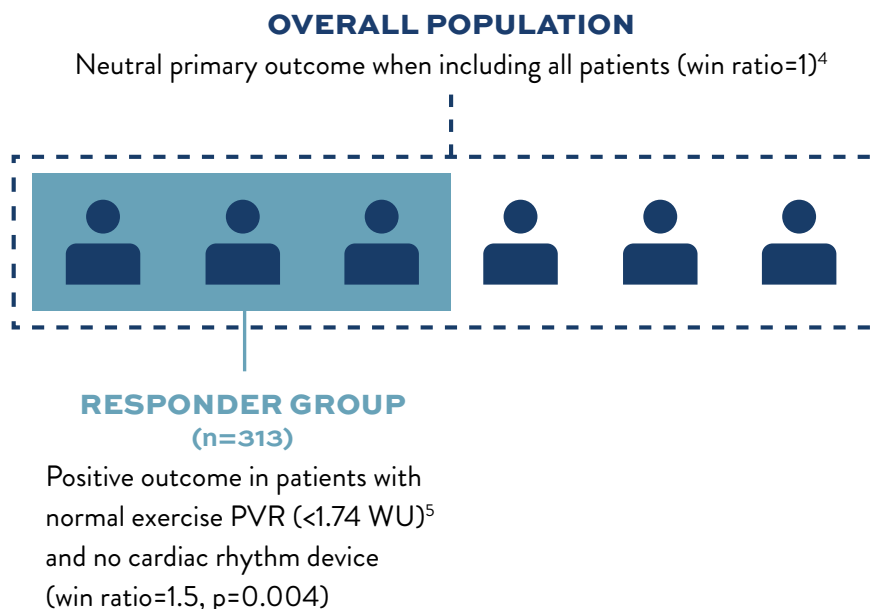
## REDUCE LAP-HF II TRIAL DESIGN<sup>1</sup>

**PURPOSE:** Evaluate the clinical efficacy and safety of the Corvia Atrial Shunt to improve quality of life and reduce HF related symptoms and events in patients with HFpEF or HFmrEF.



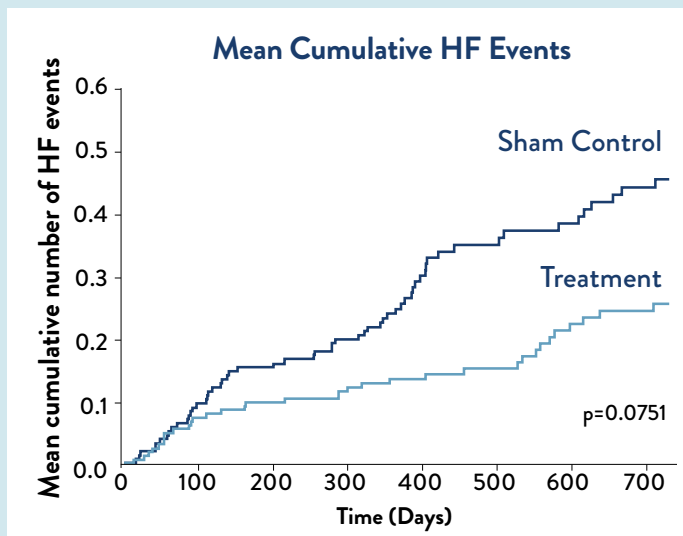
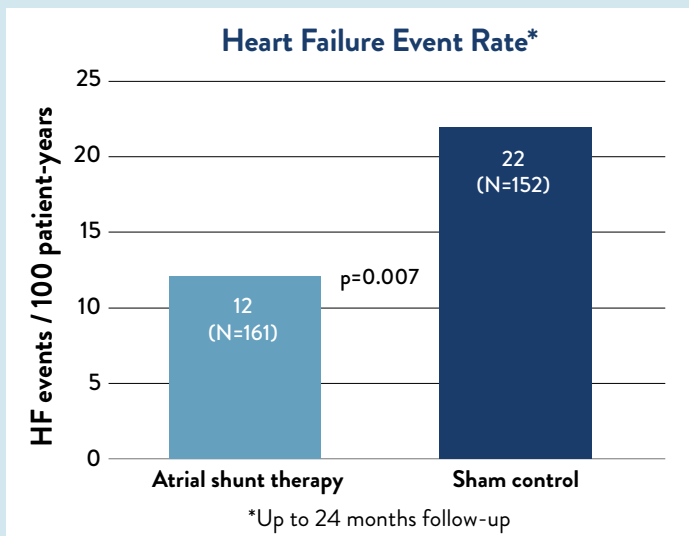
## TRIAL OUTCOME

50% of the study population benefited significantly from atrial shunt therapy despite an overall neutral trial<sup>2,3</sup>



# RESPONDER GROUP OUTCOMES (N=313)

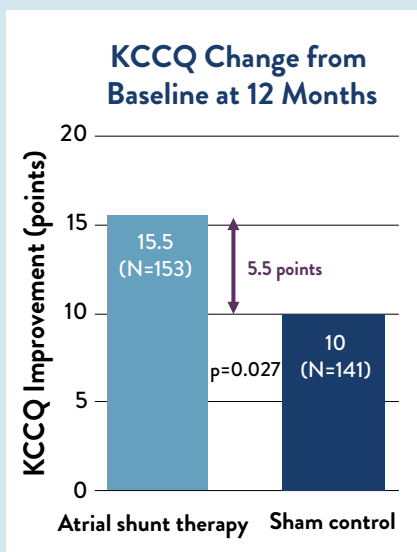
## HEART FAILURE EVENTS



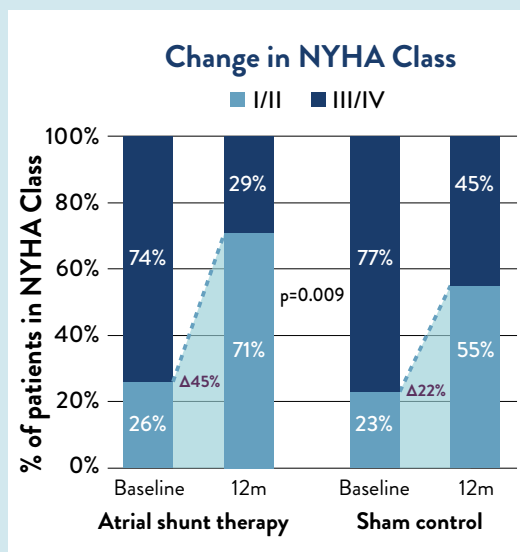
Shunt therapy led to a 45% reduction in the rate of HF events

HF event curves separate early and continue to diverge

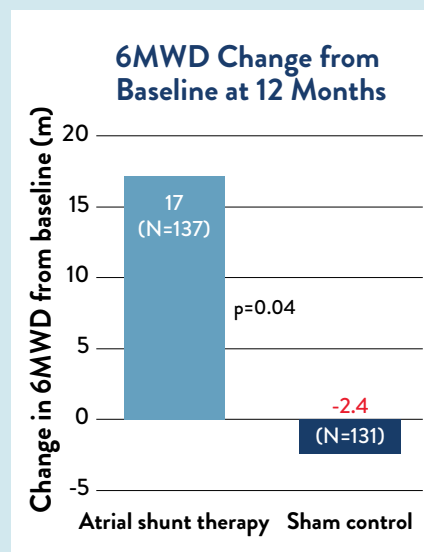
## QUALITY OF LIFE



Shunt patients had a 55% greater improvement in KCCQ



Twice as many shunt patients improved to NYHA Class I/II



Shunt patients significantly improved 6MWD

## KEY SAFETY OUTCOMES

Responder population at 1 year	Atrial Shunt therapy (N=161)	Sham control (N=152)	P-value
Cardiovascular mortality	1/161 (0.6%)	0/152 (0.0%)	0.96
Non-fatal ischemic stroke	1/161 (0.6%)	0/152 (0.0%)	0.96
New or worsening kidney dysfunction	12/161 (7.5%)	16/152 (10.5%)	0.34
Major adverse cardiac events	3/161 (1.9%)	0/152 (0.0%)	0.95
Other thrombo-embolic complications	0/161 (0.0%)	0/152 (0.0%)	—
≥30% Decrease in TAPSE	3/161 (1.9%)	3/152 (2.0%)	0.94

## LEARN MORE



Global experts Prof. Andrew Coats, Dr. Barry Borlaug, Dr. Sanjiv Shah and Prof. Gerd Hasenfuß provide insight into the REDUCE LAP-HF II responder group findings and contextualize the study results within the broader HFpEF landscape.

## CORVIA CLINICAL PROGRAM



Date indicates year enrollment completed.

### REFERENCES

1. Berry N, Mauri L, Feldman T, et al. Transcatheter InterAtrial Shunt Device for the treatment of heart failure: Rationale and design of the pivotal randomized trial to REDUCE Elevated Left Atrial Pressure in Patients with Heart Failure II (REDUCE LAP-HF II). *Am Heart J*. 2020; 226:222-31.
2. Shah SJ, Borlaug BA, Chung ES, et al. Atrial shunt device for heart failure with preserved and mildly reduced ejection fraction (REDUCE LAP-HF II): a randomised, multicentre, blinded, sham-controlled trial. *Lancet*. 2022;399(10330):1130-1140.
3. Borlaug, BA, Blair, J, Bergmann, MW et al. Latent Pulmonary Vascular Disease May Alter the Response to Therapeutic Atrial Shunt Device in Heart Failure. *Circulation*. 2022;10.1161.
4. In win ratio calculation, all patients are compared with each other in pairwise manner on values of the components in a hierarchical manner (1 = neutral, >1 treatment better, <1 sham better).
5. Upper tertile, which roughly corresponds to peak exercise in a healthy adult >55 years ( $\leq 1.8$ WU).



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### The Corvia Atrial Shunt System

is indicated for the improvement in quality of life and reduction of heart failure related symptoms and events in patients with heart failure with preserved (HFpEF) or mid-range ejection fraction (HFmrEF) with elevated left atrial pressures, who remain symptomatic despite standard Guideline Directed Medical Therapy (GDMT). See the Instructions for Use for complete information regarding the procedure, indications for use, contraindications, warnings, precautions, and potential adverse events.