

Responder HF

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<u>Trial Objective</u>	<ul style="list-style-type: none">• The primary objective of this clinical trial is to further evaluate the clinical efficacy of the Corvia Atrial Shunt in symptomatic heart failure patients with a left ventricular ejection fraction (LVEF) \geq 40%, and elevated left sided filling pressures despite standard Guideline-Directed Medical Therapy (GDMT); and to confirm the treatment effect observed in the responder group of the REDUCE LAP-HF Randomized Trial II.
<u>Randomization</u>	<ul style="list-style-type: none">• 1:1 randomization (Device vs. Sham)
<u>Key Inclusion</u>	<ul style="list-style-type: none">• Chronic symptomatic Heart failure• Ongoing stable GDMT HF management• Age \geq 40 years old
<u>Key Exclusion</u>	<ul style="list-style-type: none">• Advance heart failure defined as:<ol style="list-style-type: none">a. ACC/AHA/ESC Stage D heart failure, Non-ambulatory NYHA Class IV HFb. Cardiac index $<$ 2.0 L/min/m²c. Inotropic infusion (continuous or intermittent) for EF $<$ 40% within the past 6 monthsd. Patient is on the cardiac transplant waiting list<ul style="list-style-type: none">• Inability to preform 6 minute walk test(distance$<$50m) or 6MWT$>$600m• Participants with existing or surgically closed (with a patch) atrial septal defects• COPD, requiring continuous home oxygen