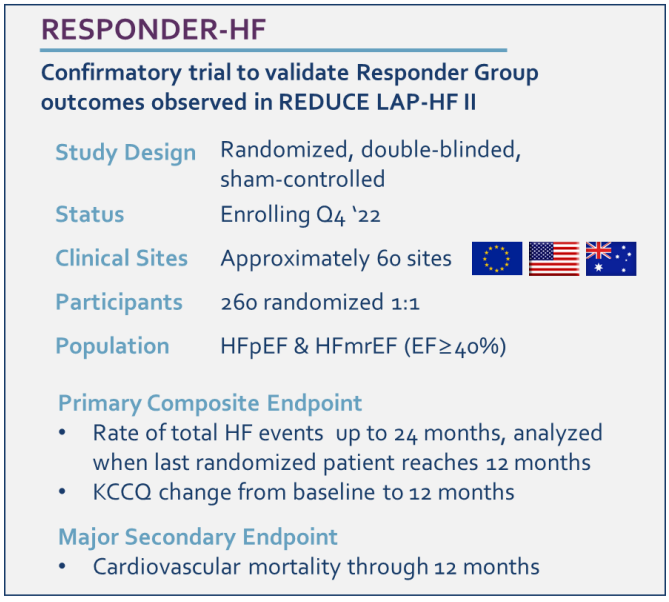
corvia®

RESPONDER-HF Trial Messaging

- RESPONDER-HF is a clinical trial with the potential to change the way heart failure (HF) is treated.
- The purpose of RESPONDER-HF is to confirm the efficacy of the Corvia Atrial Shunt as a therapy for patients diagnosed with heart failure with preserved (HFpEF) or mildly reduced ejection fraction (HFmrEF).
- The RESPONDER-HF trial builds on the extensive data and progressive learnings from the REDUCE LAP-HF II clinical trial, which was both the largest randomized controlled trial of device-based therapy and the only study of an implantable therapeutic device to show clinical benefit in this patient population. Patients in the REDUCE LAP-HF II Responder subgroup, which represented 50% of the study population, had a 45% reduction in HF events and a 55% greater improvement in health status as assessed by the Kansas City Cardiomyopathy Questionnaire (KCCQ).
- The RESPONDER-HF clinical protocol has been authorized for enrollment by FDA on June 30, 2022 to confirm the effectiveness results from REDUCE LAP-HF II.
- RESPONDER-HF will randomize up to 260 participants from investigational sites across the US, Europe, and Australia.
- The therapy will be evaluated by comparing a treatment arm to a sham control arm, meaning 50% of participants will receive the shunt and 50% will not. Patients in the sham control arm will have the possibility of receiving the Corvia Atrial Shunt 2 years after the initial procedure, thereby providing all participants with the opportunity to receive the therapy.
- The trial outcome will focus on the Corvia Atrial Shunt's impact on the rate of heart failure events and patient quality of life. Safety outcomes are also evaluated.



- More than 26 million people worldwide have HF, and over half those have HFpEF, which has been described as the largest unmet clinical need in cardiovascular medicine.
- The Corvia Atrial Shunt is designed to reduce elevated left atrial pressure (LAP), the primary contributor of HF symptoms in HF patients.
- The shunt is placed by an interventional cardiologist or electrophysiologist between the left and right atria, forming a passage that allows blood to flow from the high pressure left atrium to the lower pressure right atrium, with the aim of reducing HF symptoms and events and improving quality of life.

See the Corvia Medical Fact Sheet for additional background information on heart failure, Corvia Medical, and the Corvia Atrial Shunt.

Office: +1-978-654-6123 | Fax: +1-978-851-2668 | info@corviamedical.com | corviamedical.com

One Highwood Drive, Suite 300, Tewksbury, MA 01876 USA