

2-Year PROACTIVE-HF Trial Outcomes

Cordella is the **first** remote heart failure (HF) management platform for NYHA class III patients that combines seated pulmonary artery (PA) pressure monitoring with vital sign data. PROACTIVE-HF is the **first** pivotal trial to report 2-year outcomes using PA pressure guided heart failure management¹.

Background

Trial details²

- Prospective, multi-center, open-label trial
- **Transitioned from randomized to single-arm**
 - After N=148 randomized[^]
- **Primary endpoint** (6-mo HFH/all-cause mortality) and powered secondary endpoint (1-year HFH/all-cause mortality)
 - **Pre-specified objective performance goal** based on prior hemodynamic-guided HF trials

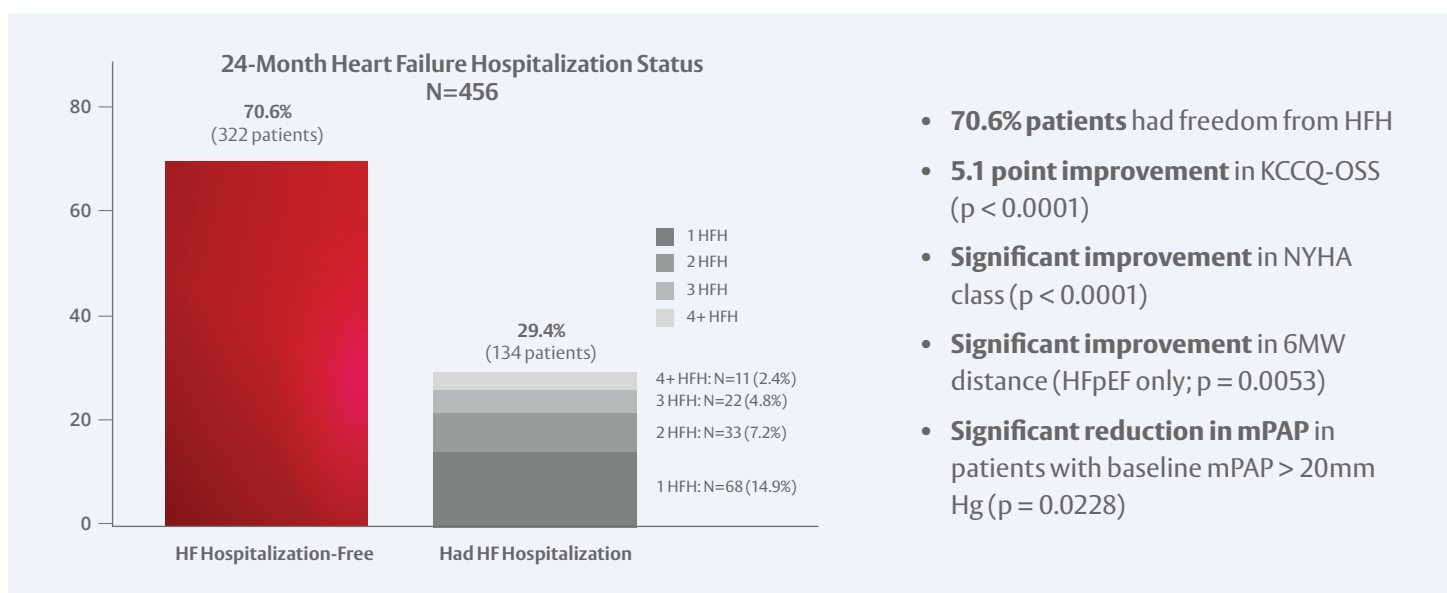
Key baseline characteristics (N=456)³

- Age (y): 63.5
- Female: 39.5% of patients
- HFrEF: 45.6% of patients
- **% Patients with ≥ 1 HFH in prior year: 80.3%**
- NT pro-BNP (pg/mL): 1731.4

1-Year Clinical Results⁴

- **Significantly lower rate of HF hospitalizations (HFH)/all-cause mortality** vs. performance goal (0.36 vs. 0.70, $p < 0.0001$)
- **Significant reduction in HFH rate** from one-year pre-implant (1.04) to one-year post-implant (0.28) ($p < 0.0001$)
- **99.2% freedom** from device or system related complications (DSRCs)*

2-Year Clinical Results¹



For important safety information, please visit cordella.com.

* Key non-DSRC related adverse or serious adverse events⁷ included hemoptysis (3.0%, all mild-moderate with full recovery); vascular access site complications (2.4%); conduction disturbances / arrhythmias (0.8%)

[^]Rationale for trial-design change, in consultation with FDA: With new evidence supporting benefit of PAP-guided HF management in NYHA III patients, there were equipoise challenges in the randomized trial from a clinical perspective, as practitioners wanted unblinded access to PAP measurements.



Edwards

2-Year Patient Compliance¹

5.8 readings

Average submissions per week

91% of patients

Submitted at least one weekly reading



Cordella enables patient-preferred⁵ **seated readings and patient access to their data** which has been shown to drive positive lifestyle choices⁶.

2-Year Clinic Compliance¹

2.4

average days between submission and acknowledgement

92%

readings met compliance target of acknowledgement within 4 days

9,624

medication changes with both up and down titrations

Conclusion

In NYHA III patients, HF management with the Cordella PA sensor system was associated with a sustained benefit including low HF hospitalization rates, improved health status, high patient and clinic compliance at 2 years¹.

For important safety information, please visit [cordella.com](https://www.cordella.com).

1. Guichard JL, Bonno EL, Nassif ME, et al. Two-year results of the PROACTIVE-HF trial stratified by LVEF. Journal of Cardiac Failure. 2026. doi.org/10.1016/j.cardfail.2026.01.023
2. Guichard JL, Cowger JA, Chaparro SV, et al. Rational and Design of the Proactive-HF Trial for Managing Patients With NYHA Class III Heart Failure by Using the Combined Cordella Pulmonary Artery Sensor and the Cordella Heart Failure System. Journal of Cardiac Failure. 2022; 29, 171-180
3. Guichard JL, Bonno EL, Nassif ME, et al. Seated pulmonary artery pressure monitoring in patients with heart failure: results of the PROACTIVE-HF trial. J Am Coll Cardiol HF. 2024;12(11):1879-1893. doi:10.1016/j.jchf.2024.05.017
4. Guichard JL, Bonno EL, Nassif ME, et al. Seated pulmonary artery pressure monitoring in patients with heart failure: 12-month outcomes of the PROACTIVE-HF trial. J Am Coll Cardiol HF. null2026, 0 (0). doi.org/10.1016/j.jchf.2025.102847
5. Sharif F, Rosenkranz S, Bartunek J, et al. Safety and efficacy of a wireless pulmonary artery pressure sensor: primary endpoint results of the SIRONA 2 clinical trial. ESC Heart Fail. 2022;9(5):2862-2872. doi:10.1002/ehf2.14006
6. Cowger JA, Guichard JL, Sharif F, et al. Engaging patients and clinicians with remote pulmonary artery pressures improves care: a sub-study of the PROACTIVE-HF clinical trial. Poster presented at: Heart Failure Society of America (HFSA) Annual Scientific Meeting; 2023; Cleveland, OH
7. Cordella Summary of Safety and Effectiveness Data (SSED) rev. 2. https://www.accessdata.fda.gov/cdrh_docs/pdf23/P230040B.pdf

In the U.S., the Cordella PA Sensor System is Rx Only. CAUTION: Federal law restricts this device to sale by or on the order of a physician. In Europe, the Cordella PA Sensor System is Exclusively for Clinical Investigation.

See [instructions for use](#) for full prescribing information. As with any medical procedure, there is a possibility of risks. The most serious risks of the Cordella PA Sensor are similar to other heart procedures and include death, serious damage to the arteries, serious bleeding, breathing problems, renal (kidney issues), and worsening heart failure.

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