

# Dafodil-1 First-In-Human Trial

## Study Highlights

- Dafodil-1 is a prospective, multi-centre, single-arm clinical study to evaluate safety and performance of the Dafodil™ Pericardial Bioprosthesis in patients who require replacement of their natural or prosthetic aortic or mitral valve. (CTRI Number: CTRI/2017/07/009008)<sup>1</sup>
- Safety and performance endpoints including hemodynamics of the valve will be evaluated till 5 years.
- The study initiated with 60 patients and has been extended to 136 patients.
- One-year clinical outcomes and hemodynamic performance of Dafodil Pericardial Bioprosthesis are published in the Journal of Cardiothoracic Surgery.
- Long-term follow-up of the study patients is currently ongoing.

## ❖ Study Design

A prospective, multicentre, single-arm clinical study



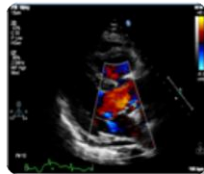
136 patients enrolled (Aortic:67; Mitral:69)



19 investigational sites across India



Clinical follow-up at 30 days, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years



Hemodynamic parameters evaluated by Independent Central Echo Laboratory (CBCC Global Research LLP, Ahmedabad, India)

## ❖ References

1. CTRI Number: CTRI/2017/07/009008  
<http://ctri.nic.in/Clinicaltrials/showallp.php?mid1=18377&EncHid=&userName=dafodil-1>
2. Hiremath, C.S., Jain, A.R., Garg, A. et al. Clinical outcomes and hemodynamic performance of Dafodil™ aortic and mitral pericardial bioprosthesis: 1-year results from Dafodil-1 first-in-human trial. J Cardiothorac Surg 15, 140 (2020). <https://doi.org/10.1186/s13019-020-01154-7>