

AltaValve Pivotal Trial

NCT06465745

Status	RECRUITING
Phase	Not Applicable
Sponsor	4C Medical Technologies, Inc.
Enrollment	450 participants

Key Eligibility Criteria

Inclusion (4)

- Age e 18 years.
- Symptomatic New York Heart Association (NYHA) class II-IV.
- Moderate-to-severe or severe MR (3+) despite optimal guideline-directed medical therapy (GDMT) as determined by an independent Echo Core Lab.
- Unsuitable for surgery and Transcatheter Edge-toEdge Repair (TEER) as determined by the local site Heart Team.

Exclusion (12)

- Inability to understand the trial or a history of non-compliance with medical advice.
- Inability to provide signed Informed Consent Form (ICF).
- History of any cognitive or mental health status that would interfere with participation in the trial.
- Currently enrolled in any other pre-approval investigational trial (does not apply to long-term post-market trials unless these trials might clinically interfere with the current trial endpoints (e.g., limit use of trial-required medication, etc.)).
- Female subjects who are pregnant or planning to become pregnant within the trial period.

... and 7 more (see full listing online)

Locations (29 total)

Abrazo Arizona Heart Hospital, Phoenix, Arizona, United States
Dignity Health; St. Joseph's Hospital and Medical Center, Phoenix, Arizona, United States
TMC Healthcare, Tucson, Arizona, United States

... and 26 more locations