

# MITRIS China Post Market Clinical Follow-up (PMCF) Study

NCT07059793

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Status	RECRUITING
Sponsor	Edwards Lifesciences
Enrollment	250 participants

## Key Eligibility Criteria

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### Inclusion (4)

- years or older at the time of informed consent
- Has a dysfunctional native or prosthetic mitral valve and requires mitral valve replacement surgery
- Provide signed written informed consent prior to the study participation
- Willingness to follow protocol requirements

### Exclusion (5)

- Active endocarditis 3 months prior to the procedure
- Stage 4 renal disease or requiring dialysis (eGFR  $\leq$  30 is excluded)
- Less than 2-year life expectancy due to non-cardiovascular life-threatening disease
- High predicted risk of mortality prior to procedure - STS Predicted Risk of Mortality (PROM)  $\geq$  8 or Surgeon estimated risk of mortality of  $\geq$  8 (STS PROM risk calculation score must be used for patients undergoing Isolated Mitral Valve Replacement (MVR) or MVR+ Coronary Artery Bypass Grafting (CABG). Surgeon estimated risk of mortality may only be used for patients who do not qualify for evaluation against those surgical models.)
- Participating in a drug or device study that has not reached its primary endpoint. Note: Participation in national registries is not an exclusion.

## Locations (13 total)

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Beijing Anzhen Hospital, Capital Medical University, Beijing, Beijing Municipality, China  
Fuwai Hospital, CAMS & PUMC, Beijing, Beijing Municipality, China  
Xiamen Cardiovascular Hospital Xiamen University, Xiamen, Fujian, China  
... and 10 more locations