

FDA initiatives to facilitate evaluation of novel percutaneous valve technologies within the US

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**Early Feasibility
Study
Program**

Early Feasibility Study Program

- Encourage medical device innovation to address clinical needs and improve patient care
- Provides the earliest and broadest patient access to beneficial medical devices
- Regaining and maintaining innovation in the US
- The core principle is the application of benefit/risk principles throughout regulatory decision-making
 - Patient tolerance for risk & perspective on benefits
 - Risk mitigation strategies when balancing risks and benefits

Early Feasibility Study Program

- Features:
 - Small number of subjects
 - Device intended for a specific indication that may be early in development, typically before the device design has been finalized
 - Does not necessarily involve the first clinical use of a device
- Just in Time Testing
 - Comprehensive testing during early phases of device development may add cost without return
 - May be acceptable to defer some testing until the device design has been finalized
 - Smaller number of samples, shorter durations

EFS in Heart Valve Arena

- Currently 10 approved EFS trials
 - Transcatheter mitral valve therapies
 - Tricuspid valve therapies
 - 2-7 months from first contact with FDA to EFS IDE approval
 - 9/10 approved within 30 days of IDE submission
- Lessons learned
 - Early and frequent interaction with FDA
 - Live demo with engineers
 - Uncertainties are expected but focus is on mitigation

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**Early Feasibility
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**Pre-/Post-market
Balance**

Pre/Post-Market Balance

- Shifting some premarket data needs to the post-market setting
- Acceptance of a greater degree of uncertainty regarding the probable benefits or risks
- Balancing the possible benefits of earlier patient access to the device, especially when the alternatives are either absent or of limited use, versus the possible risks of patient harm from exposure to an unsafe or ineffective device

Pre/Post-Market Balance

- Expedited Access Program
 - Intended for unmet medical need for life threatening or irreversibly debilitating diseases or conditions
 - Device must meet at least one of the following:
 - *No appropriate alternative treatment*
 - *Represents a breakthrough technology*
 - *Offers significant, clinically meaningful advantages*
 - *In the best interest of patients*
 - Agreement on Data Development Plan
 - Features:
 - Interactive review
 - Senior management involvement
 - Case manager
 - Priority review

FDA recommends discussing with review branch prior to submitting for EAP designation

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Use of Registries

Use of Registries for Regulatory Decisions

- CDRH Strategic Priority: Increase the use of evidence from clinical experience to support regulatory decision making
 - Already used for TAVR post-market studies
 - Potential use for pre-market data collection
- Registry data as valid scientific evidence
 - Reliable: Are the data adequate the answer the question at hand?
 - Population
 - Data checks
 - Monitoring/auditing
 - patient protection
 - Robust: Is it supported by the medical community?
 - Benchmarking and performance
 - Set practice guidelines
 - Generates peer reviewed publications
 - Allows validated predictive risk modeling
 - Sufficient for signal recognition and assessment
 - Relevant: Is aggregate data sufficient to make a regulatory decision?

Developing Partnerships

- Key aspect of implementation of FDA's initiatives
- Clinical/Academic Partnerships
 - ACC/STS: TVT Registry
 - ACC: LAAO Registry
 - VARC/MVARC efforts
 - ISO standards
- Industry Partnerships
 - Increased outreach to encourage early interactions with heart valve team
 - Increased interactions during application review



