FDA Questions for Panel

QUESTION #1. Safety and Effectiveness

Please discuss the safety and effectiveness of endovascular stent grafts in the treatment of abdominal aortic aneurysms stratified by near-term and long-term outcomes.

QUESTION #2. Clinical and Imaging Event Surveillance

A. Available long-term data demonstrate that adverse events continue to accrue post-EVAR. Please discuss which of the following real-world clinical outcomes should be assessed in a long-term EVAR surveillance system:
   - All-cause mortality
   - Aneurysm-related mortality
   - Aortic rupture
   - Aortic reinterventions
   - Others

B. Although imaging outcomes are collected in pre-market and FDA-required post-market studies, these studies have a modest sample size, and it is challenging to collect serial imaging data in real-world surveillance. Please discuss the importance and feasibility of the capturing the following imaging outcomes in real-world surveillance:
   - Endoleaks
   - Loss of device integrity
   - Aortic enlargement
   - Device migration
   - Device patency

QUESTION #3. Real-world Surveillance

Please discuss whether strengthening existing real-world surveillance is needed to evaluate long-term EVAR performance. If so, please address the following:

A. Please discuss the key attributes that should be included in a real-world surveillance infrastructure to assure high quality and clinically useful long-term EVAR device evaluation (e.g., enrollment strategies to address potential selection bias, data monitoring and auditing, event adjudication, core labs, major endpoints, statistical analysis plan).

B. Please discuss the frequency and duration of surveillance for patients post-EVAR that would be clinically meaningful and feasible to capture through a real-world surveillance infrastructure, including recommendations for patients who undergo aortic reintervention.

C. Please discuss strategies that can incentivize relevant stakeholders to participate in real-world data collection on a routine basis.

D. Please comment on how device manufacturers, health care systems, professional societies, individual providers, and other stakeholders should collaborate to maximize long-term follow-up compliance and data quality on EVAR device performance.