Alliance FOR AGING RESEARCH

Catalyzing Innovation for Healthy Aging

Public Meeting: Medical Device User Fee Amendments for Fiscal Years 2023 Through 2027

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The Alliance for Aging Research is the leading non-profit organization dedicated to accelerating the pace of scientific discoveries and their application in order to vastly improve the universal human experience of aging and health.

www.agingresearch.org

Catalyzing Innovation for Healthy Aging

Investment in Digital Health Infrastructure

- Growth in development and approval needs for digital technologies and apps
- Expanded scope of review expertise to address technology, communication, and privacy concerns
- MDUFA V should prioritize investment in infrastructure for review and surveillance of digital technologies

Patient Access to Device Benefit-Risk Reduction

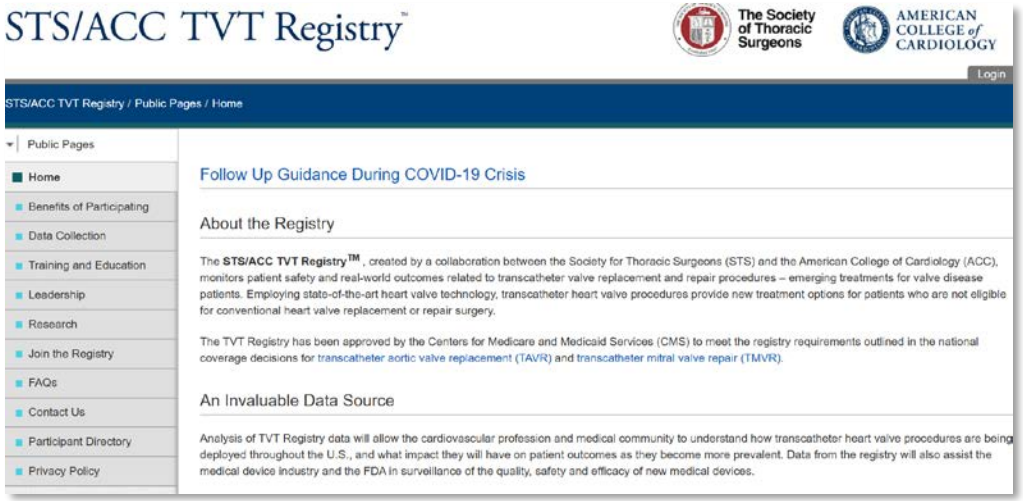
- Access to device benefit-risk information differs for devices
- Patients may have less opportunity to review benefit-risk information and understand alternatives
- Invest in patient engagement around communication of benefit-risk information and work with provider groups to incorporate into workflows

Data Transparency in Patient Registries

- Access to device registry data needed for post-approval information on outcomes and efficacy

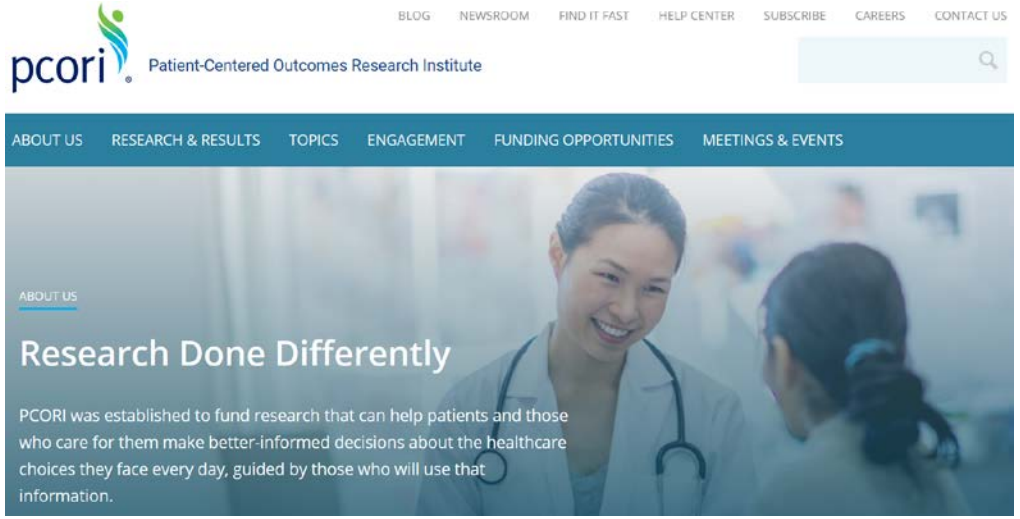
- Lack of transparency and public availability of registry data creates barriers to the timely evaluation of outcomes

- Recommend engagement to ensure regular reporting of outcomes to support post-approval evaluation and to empower patients



Advancing Evidence on Patient-Centered Outcomes

- PCORI was reauthorized last year and has an expanded scope in evaluating outcomes for patients and other stakeholders
- Opportunity to coordinate and collect real-world evidence on patient-centered outcomes that evaluate comparative effectiveness of devices
- Recommend engagement of CDRH in a strategic research partnership with PCORI



Support for MDUFA Reauthorization

- Timely MDUFA reauthorization will help ensure that the FDA keeps pace with scientific discovery and helps bring the next generation of safe and effective devices to patients

- MDUFA V provides an opportunity to invest in infrastructure to support and improve access to outcomes data

- The Alliance for Aging Research looks forward to working collaboratively with the FDA, device manufacturers, and other stakeholders to enhance the existing MDUFA program