

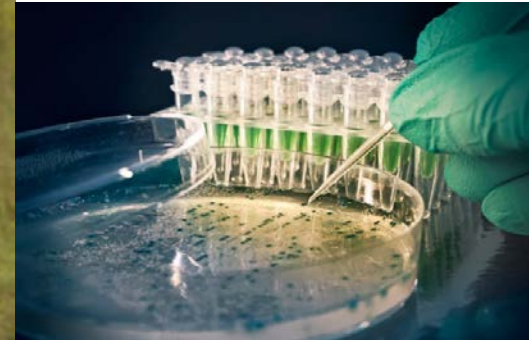


**Catalyzing Innovation
for Healthy Aging**

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

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



The screenshot shows the registration page for the Patient Engagement Forum, an MDIC event. At the top right, it says "NOVEMBER 18, 2020 • VIRTUAL EVENT" and "A CONVENING OF PATIENTS, PHYSICIANS, INDUSTRY AND REGULATORS". A prominent button says "REGISTER TODAY!". Below this is a navigation menu with links: HOME, SCHEDULE, SUPPORT, SPEAKERS, RESOURCES, AGENDA, ATTENDEE GUIDE, REGISTER. The main content area includes a login form with fields for "Email Address" and "Password" (with a "lost password?" link), a "remember me" checkbox, and "Login" and "Create Login" buttons. The MDIC logo (Medical Device Innovation Consortium) is displayed. A paragraph describes the forum's purpose: "MDIC's Virtual Patient Engagement Forum will provide interactive opportunities to engage with patients, patient engagement advocates, medical device industry, regulators, physicians, payers and experts in communication and shared decision making to learn and share challenges about best practices for communicating benefit, risk, and uncertainty for medical devices to patients." Below this, a section titled "During the forum:" lists five key activities, each with an icon: 1. A magnifying glass icon: "We will share the key findings on challenges and best practices for communicating benefit risk and uncertainty for medical devices from our recently released MDIC Communication Report." 2. A gear icon: "Experts in shared decision-making and communication will discuss best practices for communicating patient preference information in device labeling and shared decision-making to understand how engaging patients can help tailor effective messaging." 3. A speech bubble icon: "Participants will hear patients' perspectives on their first-hand experience with these types of communications during our two patient panel sessions and two interactive activities." 4. A briefcase icon: "Attendees who register for the Interactive Activities will have an opportunity to participate in a real-time application of the tools and techniques discussed during the forum by engaging in small, multi-stakeholder interactive virtual break-out sessions. The groups will discuss their experiences, share challenges and brainstorm possible solutions with these types of communications." 5. A lightbulb icon: "Attendees will help shape the output for the MDIC initiative as a companion report summarizing learnings and key takeaways from the forum will be created to supplement the MDIC report." At the bottom, a section titled "WHO SHOULD ATTEND?" features six icons representing different groups: Patients, Patient Engagement Advocates, Regulators, Medical Device Industry, Physicians, and Payers. A "Register Here" button is located at the bottom right of this section.

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

STS/ACC TVT Registry™



STS/ACC TVT Registry / Public Pages / Home

Public Pages

- Home
- Benefits of Participating
- Data Collection
- Training and Education
- Leadership
- Research
- Join the Registry
- FAQs
- Contact Us
- Participant Directory
- Privacy Policy

Follow Up Guidance During COVID-19 Crisis

About the Registry

The STS/ACC TVT Registry™, created by a collaboration between the Society for Thoracic Surgeons (STS) and the American College of Cardiology (ACC), monitors patient safety and real-world outcomes related to transcatheter valve replacement and repair procedures – emerging treatments for valve disease patients. Employing state-of-the-art heart valve technology, transcatheter heart valve procedures provide new treatment options for patients who are not eligible for conventional heart valve replacement or repair surgery.

The TVT Registry has been approved by the Centers for Medicare and Medicaid Services (CMS) to meet the registry requirements outlined in the national coverage decisions for transcatheter aortic valve replacement (TAVR) and transcatheter mitral valve repair (TMVR).

An Invaluable Data Source

Analysis of TVT Registry data will allow the cardiovascular profession and medical community to understand how transcatheter heart valve procedures are being deployed throughout the U.S., and what impact they will have on patient outcomes as they become more prevalent. Data from the registry will also assist the medical device industry and the FDA in surveillance of the quality, safety and efficacy of new medical devices.

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

