



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

A screenshot of the MDIC Virtual Patient Engagement Forum website. The header features the text "PATIENT ENGAGEMENT FORUM AN MDIC EVENT" and "NOVEMBER 18, 2020 • VIRTUAL EVENT A CONVENING OF PATIENTS, PHYSICIANS, INDUSTRY AND REGULATORS" with a "REGISTER TODAY!" button. The main content area includes a "Login" form, a "During the forum:" section with five bullet points, a "WHO SHOULD ATTEND?" section with icons for Patients, Patient Engagement Advocates, Regulators, Medical Device Industry, Physicians, and Payers, and a "Register Here" button.



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™

A screenshot of the STS/ACC TVT Registry website. The header features the logos of The Society of Thoracic Surgeons (STS) and the American College of Cardiology (ACC). The main content area is titled "STS/ACC TVT Registry™" and includes sections for "Follow Up Guidance During COVID-19 Crisis", "About the Registry", and "An Invaluable Data Source". The left sidebar contains a navigation menu with links to Home, Benefits of Participating, Data Collection, Training and Education, Leadership, Research, Join the Registry, FAQs, Contact Us, Participant Directory, and Privacy Policy.



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

