2016 Annual Public Forum

Gathering industry, government, and nonprofit partners to advance the regulatory science of medical devices.

Wednesday, September 21, 2016 | 9:00 a.m. to 4:00 p.m. ET

Reagan Building and International Trade Center
1300 Pennsylvania Ave NW | Washington, DC

The 2016 Annual Public Forum will gather MDIC members and the broader medical device and diagnostics community to share insights on current trends in regulatory science and the progress MDIC has made in advancing the field. MDIC works collaboratively to advance regulatory science by developing new tools, methods, and processes with our partners across government, industry, and non-profit organizations. Our goal remains improving patient access to safe and effective cutting-edge technologies with a special focus on patient engagement and innovative approaches to clinical evidence and clinical trial design. In addition to the in-person seminar, the meeting will be broadcast in webinar format for those who may be unable to attend in-person.

8:30 a.m. **Security check-in and Continental Breakfast**

9:00 a.m. **Welcome**
Bill Murray | President & CEO, MDIC

9:05 a.m. **Keynote Address**
FDA Vision for the Future & the Role of Real-World Evidence in Innovation
Robert Califf, MD | Commissioner, FDA

9:35 a.m. **A Conversation with Commissioner Califf**
Robert Califf, MD | Commissioner, FDA
Mike R. Minogue | Abiomed, President, CEO, and Chairman; MDIC Board Chairman

10:00 a.m. **CDRH Vision & Priorities**
Jeff Shuren, MD, JD | Director, CDRH FDA

10:25 a.m. **MDIC Strategy & Priorities**
Bill Murray | President & CEO, MDIC

10:40 a.m. **Break**

10:50 a.m. **Panel Discussion: Patient Engagement**
CDRH has identified partnering with patients as an important strategic priority and with the 2016 release of final guidance on patient preferences, many device sponsors are exploring how to engage patients in the medical device development and regulatory process. This panel brings together patients, CDRH and sponsor stakeholders to discuss patient perspectives in regulatory benefit-risk decision making, notable progress, tips for how device companies can better engage with patients and areas of opportunity.
Moderator: Suzanne Schrandt, JD | Director of Patient Engagement, Arthritis Foundation
Marc Boutin, JD | CEO, National Health Council
Kelly L. Close | President, Close Concerns, Founder, The diaTribe Foundation
Kathryn O'Callaghan | Assistant Director for Strategic Programs (Acting), CDRH FDA
Sally Okun, RN, MMHS | Vice President Advocacy, Policy and Patient Safety, PatientsLikeMe
Peter Saltonstall | President & CEO, National Organization for Rare Disorders (NORD)

11:50 a.m. **Lunch**

12:20 p.m. **Panel Discussion: Addressing the Evidence Development Resource vs. Access Challenge**
Increasingly, stakeholders are requiring greater evidence generation from clinical trials. MDIC's approach is a sustainable data aggregating model which leverages existing resource investments to meet evidence and patient access demands.

Preceding this panel, Dawn Bardot and Roseann White will give updates on MDIC's working group progress
Dawn Bardot, PhD | Vice President, Technology Innovation, MDIC
Roseann White | Director of Pragmatic Clinical Trial Statistics, Duke Clinical Research Institute

Moderator: Dan Schwartz | ACTP Program Manager, MDIC
Owen Faris, PhD | Clinical Trials Director, Office of Device Evaluation, CDRH FDA
Lisa Griffin Vincent, MA, PhD | Vice President Corporate Development, Medical Affairs, Office of Science, Medicine and Technology, BD
Tarek Haddad | Sr. Manager, Modeling Integration and Statistics, Medtronic Cardiac Rhythm and Heart Failure
Michelle McMurry-Heath, MD, PhD | Vice President & Global Head of Regulatory Affairs, Medical Devices, Johnson & Johnson

1:20 p.m. **Break**

1:30 p.m. **Introduction of Afternoon Keynote**
Bill Murray | President & CEO, MDIC

1:35 p.m. **Medical Device National Evaluation System for Health Technologies (NEST): Planning Board Recommendation & Go Forward Plan**
Mark B. McClellan, MD, PhD | Director, Duke-Robert J. Margolis, MD, Center for Health Policy and Robert J. Margolis, MD Professor of Business, Medicine and Health Policy, Fuqua School of Business, Duke University

2:25 p.m. **Updates of Key MDIC Initiatives**
Bill Murray | President & CEO, MDIC

2:30 p.m. **Case for Quality**
Robin Newman, MSN, EdD | Director, Office of Compliance, CDRH FDA
Beth Staub | Vice President, Global Regulatory Affairs and Quality Assurance, Stryker

2:45 p.m. **Clinical Diagnostics**
Alberto Gutierrez, PhD | Director, Office of In Vitro Diagnostic and Radiological Health, CDRH FDA
Richard Naples | Executive Vice President and Chief Regulatory Officer, BD

3:00 p.m. **Panel Discussion on Key MDIC Projects**
Moderator: Dawn Bardot, PhD | Vice President, Technology Innovation, MDIC
Chip Hance | Former CEO, Creganna Medical
Ross Jaffe, MD | Managing Director, Versant Ventures
Richard E. Kuntz, MD, MSc | Senior Vice President and Chief Scientific, Clinical and Regulatory Officer, Medtronic
Randall Schiestl | Vice President, Global Technology, Boston Scientific Corporation
Suzanne Schwartz, MD | Associate Director for Science and Strategic Partnerships, CDRH FDA
Kyle Myers, PhD | Acting Director, Office of Science and Engineering Laboratories, CDRH FDA

4:00 p.m. **Closing Remarks**
Bill Murray | President & CEO, MDIC