MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM
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2015 Annual Public Forum

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

Friday, September 25, 2015 | 9:00 a.m. to 3:00 p.m. ET
The Pew Charitable Trusts | 901 E Street NW | Washington, D.C. 20004

The Annual Public Forum is an opportunity for members of MDIC and the broader medical device community to network, learn what MDIC and our partners have accomplished, and find out what's ahead. In addition to the in-person seminar, the meeting will be broadcasted in webinar format for those who may be unable to attend in-person.

Agenda of the Day

8:30 a.m. Security check-in and coffee / refreshments

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

9:15 a.m. **Keynote Addresses**
The Value of Public-Private Partnerships in Advancing Regulatory Science and Innovation
Robert Califf, MD | Deputy Commissioner Medical Products & Tobacco, FDA

MDIC's Journey from Vision to Reality and its Impact on Medical Device Innovation

Industry Perspective:
Bill Hawkins | Retired Chairman & CEO Medtronic; Lead Director, Immucor and Chairman, MDIC

CDRH Perspective:
Jeff Shuren, MD, JD | Director, CDRH FDA

10:15 a.m. **Panel Discussion: Future Opportunities for PPP's in Regulatory Science**
Moderator: Bill Murray | President & CEO, MDIC
Jeff Shuren, MD, JD | Director, CDRH FDA
Bill Hawkins | Retired Chairman & CEO Medtronic; Lead Director, Immucor and Chairman, MDIC
Michelle McMurry-Heath MD, PhD | WW Vice President, Regulatory Affairs Medical Devices, Johnson & Johnson

10:45 a.m. Break

11:00 a.m. **FDA Regulatory Science Priorities**
Anindita Saha | Director of External Expertise and Partnerships, CDRH FDA

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MDIC Project Updates

11:15 a.m. **Clinical Trials Innovation & Reform (CTIR) Project Update**
Stephanie Christopher | Program Manager, MDIC
Karim Benali, MD | Vice President and Chief Medical Officer, Abiomed
Owen Faris, PhD | Clinical Trials Director (Acting), CDRH FDA

11:45 a.m. **Computer Modeling & Simulation (CM&S) Project Update**
Dawn Bardot, PhD | Senior Program Manager, MDIC
Randy Schiestl | Vice President, Global Technology, Boston Scientific
Kyle Myers, PhD | Director, Office of Science and Engineering Laboratories (Acting), CDRH FDA

12:15 p.m. Lunch break

12:45 p.m. **Patient Centered Benefit-Risk (PCBR) Project Update**
Stephanie Christopher | Program Manager, MDIC
Ross Jaffe, MD | Director, National Venture Capital Association and Managing Director, Versant Ventures
Kathryn O'Callaghan | Associate Center Director for Science and Strategic Partnerships (Acting), CDRH FDA

Panel: Future Opportunities in Patient Preferences
Moderator: Ross Jaffe, MD | Director, National Venture Capital Association and Managing Director, Versant Ventures
Robert Becker, MD, PhD | Chief Medical Officer, Office of In Vitro Diagnostics and Radiological Health, CDRH FDA
Telba Irony, PhD | Acting Head, Quantitative Innovation Program, CDRH FDA
Bryan Luce, PhD | Chief Science Officer, PCORI
Michelle McMurry-Heath MD, PhD | WW Vice President, Regulatory Affairs, Medical Devices, Johnson & Johnson
Kathryn O'Callaghan | Associate Center Director for Science and Strategic Partnerships (Acting), CDRH FDA

1:45 p.m. **Clinical Diagnostics (CDx) Project Update**
Carolyn Hiller | Program Manager (Acting), MDIC
Steve Binion, PhD | Director Corporate Regulatory Affairs, BD

2:00 p.m. **Case for Quality (CfQ) Project Update**
Suzanne Fiorino | Program Manager (Executive on Loan from Johnson & Johnson), MDIC
Aran Maree, MD| Chief Medical Officer, Medical Devices & Diagnostics, Johnson & Johnson
Jan Welch | Director, Office of Compliance (Acting), CDRH FDA

2:30 p.m. **MDIC Future Vision**
Bill Murray | President & CEO, MDIC

2:45 p.m. **Q&A**
Kathryn O'Callaghan | Associate Center Director for Science and Strategic Partnerships (Acting), CDRH FDA
Bill Murray | President & CEO, MDIC

3:00 p.m. **Adjourn**