

Join us Oct 3rd at the 2017 MDIC Annual Public Forum

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

9:00 a.m. **Welcome**

Bill Murray | President & CEO, MDIC

9:05 a.m. **Keynote Address**

Scott Gottlieb, MD | Commissioner, FDA

9:50 a.m. **Panel Session**

Moderator: Mike Minogue | President, CEO, and Chairman, Abiomed; MDIC Board Chairman

Jeff Shuren, MD, JD | Director, CDRH FDA

Mark Leahey | President & CEO, MDMA

Kim McCleary | Acting Executive Director and Managing Director, FasterCures

Scott Whitaker | President & CEO, AdvaMed

10:35 a.m. *Break*

10:55 a.m. **MDIC Plenary**

Bill Murray | President & CEO, MDIC

11:25 a.m. **Developments with the National Evaluation System for health Technology Coordinating Center (NESTcc): A Discussion with Members of the NESTcc Governing Committee**

Moderator: Rachael Fleurence, PhD | Executive Director, NESTcc

Adrian Hernandez, MD | Vice Dean for Clinical Research, Duke University School of Medicine

Michelle McMurry-Heath, MD, PhD | Worldwide Vice President, Regulatory Affairs and Clinical

Research, Johnson & Johnson Medical Devices

Jeff Shuren, MD, JD | Director, CDRH FDA

12:10 p.m. *Lunch*

Social Lounge

Innovation Center

1:15 p.m. **Why patient input matters**

Barry Liden, JD | Edwards Lifesciences

Moderator: Barry Liden, JD | Edwards

Kara Haas, MD | Johnson & Johnson

Chad Mather, MD | Duke Orthopaedics, DCRI

Lauren McLaughlin | Michael J. Fox

Annie Saha | OCD, CDRH FDA

Margaret Sheehan, JD | Ashurst LLP

Sandra Statz | Exact Sciences

Clinical Diagnostics

Don St. Pierre | OIR, CDRH FDA

April Veoukas, JD | Abbott

Moderator: Danelle Miller, JD | Roche

Steve Binion, PhD | BD

Jaime Houghton | Sysmex America, Inc.

Don St. Pierre | OIR, CDRH FDA

April Veoukas, JD | Abbott

Jeff Zinza | Hologic, Inc

Vicki Anastasi | ICON plc

2:15 p.m. *Break*

Break

2:30 p.m. **Innovation and Efficiency in Evidence**

Dawn Bardot, PhD | MDIC

Moderator: Jennifer Kerr | Cook Group

Randy Schiestl | Boston Scientific

Jijo James, MD | Johnson & Johnson

Chip Hance | Regatta Medical

Owen Faris, PhD | ODE, CDRH FDA

Mark Carlson, MD | Abbott

Naomi Aronson, PhD | Blue Cross Blue Shield

Case for Quality

Beth Staub | Stryker

Moderator: Beth Staub | Stryker

Luann Pendy, PhD | Medtronic

Robin Newman, EdD | OC, CDRH FDA

Cynthia Grossman, PhD | FasterCures

Merle Goddard | Baxter

Al Crouse | CVRx

3:30 p.m. *Break*

3:45 p.m. **Emerging Themes Keynote**

Shahram Ebadollahi, PhD | Vice President,

Innovations and the Chief Science Officer, IBM Watson Health

4:30 p.m. **Closing Remarks**

Bill Murray | President & CEO, MDIC

Session Descriptions

Join us in person or via webcast on October 3 during MDIC's Annual Public Forum for morning discussions with FDA, MDIC members and broader medical device and diagnostics community who will share vision and strategy for cultivating innovation in clinical trial design, collecting real-world evidence for use in regulatory decision making, and including patients as strategic partners in medical device development.

Morning Panel Session

A panel of leaders from industry, FDA, and nonprofit organizations will share their thoughts and insights on the role MDIC has played and will continue to play as a leading organization in bringing thought leaders together to collaborate on advancing regulatory science for patient benefit. Also learn about key medical device ecosystem trends and priorities for the future.

Developments with the National Evaluation System for health Technology Coordinating Center (NESTcc): A Discussion with Members of the NESTcc Governing Committee

In the last year since the FDA awarded MDIC a grant for the National Evaluation System for health Technology Coordinating Center (NESTcc), progress has been underway to develop and implement strategic priorities for NESTcc. This summer, the inaugural members were named to the NESTcc Governing Committee—a diverse group of stakeholders who will help drive the strategic vision for NESTcc. Moderated by Dr. Fleurence, the Executive Director of NESTcc, three members of the NESTcc Governing Committee will discuss the current developments, strategic priorities, and future opportunities of NESTcc from the perspective of the FDA, industry and the clinical research world.

Why Patient Input Matters

Multiple stakeholders share their perspective on the value of patient input across the total product life cycle and how patient input impacts development, testing, and delivery of medical device technologies to meet patients' needs. This panel discussion will engage attendees to explore the areas in which MDIC can bring all stakeholders together to develop scientifically rigorous tools to support patient input in medical device development.

Innovation and Efficiency in Evidence Generation

Sharing of the strategic vision and overview of ongoing MDIC projects to support expedited evidence generation throughout the total product life cycle. Panelists will engage in discussions on hurdles and opportunities to broad adoption and utilization of tools and best practices developed via these projects.

Clinical Diagnostics

FDA will provide an overview of strategic priorities for IVD tests. In addition, an overview of MDIC Clinical Diagnostic projects will be presented with highlights of the recently released Surrogate Sample Framework.

Case for Quality

Leaders from the medical device industry and FDA will discuss the value of the CDRH Voluntary Medical Device Manufacturing and Product Quality pilot announced earlier this summer, and how MDIC is leading in the development of a Maturity Model and Analytics initiative to build the Case for Quality.