Program
September 12 & 13, 2022
TRANSFORMING HEALTHCARE FOR GENERATIONS TO COME

The pandemic has forever changed how we think about health. Now, more than ever, we want more information, better connection, personalization and convenience.

New technologies that make it possible to deliver precise, personalized treatment, wherever you are. New ways to deliver accessible, convenient care to every corner of the world. New partnerships designed to solve access and equity challenges we can’t tackle alone.

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Abbott
**September 12, 2022**

**Annual Patient Forum**  
**Room: Pennsylvania Avenue Terrace**

An informative discussion with accomplished patients and MedTech experts on transforming patient engagement throughout the Total Product Life Cycle. Learn how the industry is leveraging patient science and inputs in improving the overall healthcare continuum. Interact with our diverse panelists of industry leaders, patients, and regulators.

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
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</thead>
<tbody>
<tr>
<td>8:00 – 9:00 am</td>
<td>Breakfast &amp; Registration</td>
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<tr>
<td>9:00 – 9:15 am</td>
<td><strong>Opening Remarks</strong></td>
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<td><em>Speakers:</em></td>
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<td></td>
<td>• Heidi Dohse, President, Founder, Tour de Heart; Patient Advocate</td>
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<td></td>
<td>• Andrew Fish, President &amp; CEO, Medical Device Innovation Consortium</td>
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<td>• Joseph Sapiente, Vice President of Clinical Science and Technology, Medical Device Innovation Consortium</td>
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<tr>
<td>9:15 – 10:00 am</td>
<td><strong>Patient Engagement in Clinical Trials and Early Development</strong></td>
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<td><em>Speakers:</em></td>
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<td></td>
<td>• Amye Leong, President &amp; CEO, Healthy Motivation</td>
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<td></td>
<td>• Stephanie Reffey, Patient Advocacy and Alliance Relations Director, Exact Sciences</td>
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<td></td>
<td>• Annabel de Maria, Vice President, Patient Engagement, Alira Health</td>
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<td>• Bill Schulz, Consultant, Alira Health</td>
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<td>10:00 – 10:45 am</td>
<td><strong>Patient-focused Digital Health and the Healthcare Continuum</strong></td>
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<td><em>Speakers:</em></td>
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<td></td>
<td>• Ami Mehr, Vice President Strategy, Vault CDMS MedTech, Veeva</td>
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<td></td>
<td>• Heather Colvin, Director, MD, Regulatory Affairs Evidence &amp; Outcomes Policy, Johnson &amp; Johnson</td>
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<td>• Brian Edwards, Regulatory Fellow – Digital Health &amp; Security, Boston Scientific</td>
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<tr>
<td></td>
<td>• Heidi Dohse, President, Founder, Patient Advocate, Tour de Heart</td>
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<tr>
<td>10:45 – 11:00 am</td>
<td>Break</td>
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11:00 am – 12:00 pm  Industry Lens: Patient Engagement During Total Product Life Cycle – Panel Discussion

Patients are not only in the forefront of defining device interoperability of digital health tools but are also the end users with feedback and vast use data. Leaders from the medical device community will talk about processes and opportunities on how their organizations engage and leverage patient experience and inputs.

Speakers:

• Heidi Dohse, President, Founder, Tour de Heart; Patient Advocate
• Kathryn Capanna, Deputy Director, Division of All Hazards Response, Science, and Strategic Partnerships
• Aaron Goodstein, Senior Director, Medical Safety Operations, Medical Devices & Global External Innovation, Johnson & Johnson
• Korinne Jew, PhD, Senior Director, Clinical Research & Medical Science, Medtronic
• Liz Mino, PhD, Sr. Principal Field Clinical Engineer, Cardionomic Inc.
• Shilpa Patel, Director, Innovation Development, American College of Cardiology

12:00 – 1:00 pm  Patient Lived-Experience Panel – “What the Device Manufacturers Should Know About Me”

Patients are the inspiration for innovation and discoveries in healthcare. In this panel, patients will share their own experiences, insights, and perspectives on what industry should know about patients and how to engage collaboratively to create efficient pathways for their patient cohorts.

Speakers:

• Dan Stephens, PhD, Global Advocacy Fellow, Boston Scientific
• Maddie Gittens, Patient
• Maria Gmitro, President & Founder, Breast Implant Safety Alliance
• Greg Guinther, Patient
• Erich Lin, Patient

1:00 – 1:10 pm  Closing remarks

Speakers:

• Heidi Dohse, President, Founder, Tour de Heart; Patient Advocate
• Kert Gunasekaran, Program Director, Science of Patient Input, Medical Device Innovation Consortium

1:10 – 2:30 pm  Lunch

Room: Congressional Room
Transforming the lives of two people every second, every hour, every day.
MedTech Cybersecurity Summit  
Room: Pennsylvania Avenue Terrace

Managing cybersecurity in healthcare is a shared responsibility. The COVID-19 pandemic has accelerated the arrival of the digital era in many aspects of global healthcare and so has the need for addressing cybersecurity concerns associated with medical devices and healthcare delivery. Medical device manufacturers and healthcare delivery organizations are now working independently and collaboratively in pre-competitive space to address cybersecurity vulnerabilities and threats. Recent efforts from the FDA and its global counterparts confirm the need to tackle cybersecurity with a multipronged approach. Public-private partnerships such as MDIC convene stakeholders to build innovative tools and resources to advance the cybersecurity of medical devices and healthcare delivery organizations. MDIC MedTech Cybersecurity Summit attendees will have the chance to learn about the global cybersecurity landscape by interacting with senior thought leaders from FDA and the private sector.

1:15 – 1:45  
Registration and Lunch

1:45 – 2:00 pm  
Opening Remarks  
Speakers:  
• Andrew Fish, President & CEO, Medical Device Innovation Consortium  
• Joseph Sapiente, Vice President of Clinical Science and Technology, Medical Device Innovation Consortium

2:00 – 2:55 pm  
MDIC Cybersecurity Maturity Benchmarking Report & Panel Discussion  
A rapidly changing cyber threat landscape results in many new threat avenues. As with any part of the medical industry, patient safety is an added concern, particularly within the medical technology industry. The MDIC MedTech cybersecurity maturity benchmarking report aims to help identify the industry’s implementation of security measures. This first of its kind, benchmarking report aims to help protect patients and the rest of the medical industry from a broad range of cybersecurity threats.  
Moderator: Colin Morgan, Managing Director, Apraciti  
Speakers:  
• Andrew Speirs, Principal, Booz Allen  
• Greg Garcia, Executive Director, Cyber Security, Health Sector Council  
• Robert Suarez, Vice President, Chief Information Security Officer, BD  
• Linda Ricci, Director, Division of All Hazards Response, Science and Strategic Partnerships, FDA

2:55 – 3:00 pm  
Break
3:00 – 3:55 pm  **Improving Penetration Testing Practices in MedTech: Panel Discussion**
Penetration testing has become an essential required practice by regulatory agencies as evidence to validate security controls and adequately resist modern attack methods under simulated real-world conditions. However, the practices of how to scope, resource, execute, respond, and report to penetration tests still lack maturity. The panel will discuss current state along with providing status and a preview of an MDIC effort to capture medical device penetration testing best practices.

**Moderator:** Chris Reed, Director of Digital Health and Product Security Policy, Medtronic

**Speakers:**
- Joshua Berry, Principal Consultant, MedSec
- Matthew Hazelett, Digital Health Center of Excellence Program Director, OPEQ Cybersecurity Focal Point Program, FDA
- Dan Lyon, Director of Product Cybersecurity, Boston Scientific

3:55 – 4:00 pm  **Break**

4:00 – 5:00 pm  **FDA CyberMed Townhall/International Medical Device Regulators Forum Updates**

**Speakers:**
- Suzanne Schwartz, MD, Director, Office of Strategic Partnerships & Technology Innovation (OST), FDA
- Aftin Ross, PhD, Senior Special Advisor for Emerging Initiatives, Office of Strategic Partnerships & Technology Innovation (OST), FDA
- Linda Ricci, Director, Division of All Hazards Response, Office of Product Evaluation and Quality (OPEQ), FDA
- Matthew Hazelett, Digital Health Center of Excellence Program Director OPEQ Cybersecurity Focal Point Program, FDA
- Jessica Wilkerson, Senior Cybersecurity Policy Advisor, Office of Strategic Partnerships & Technology Innovation (OST), FDA

5:00 – 5:15 pm  **Closing Remarks**

5:15 pm  **Dinner at MXDC**
Cybersecurity Dinner Location:
Restaurant MXDC
600 14th St NW STE 700, Washington, DC 20005
Meet Our Drivers of Innovation

Johnson & Johnson MedTech employees are engineers, designers, and educators. They’re outside-of-the-box thinkers, question-askers, movers and shakers dedicated to removing limitations to a full life.

Discover their passion for advancing health through technology.

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Annual Public Forum Agenda

8:00 – 9:00 am  Breakfast & Registration
Room: Pennsylvania Avenue Terrace

9:00 – 9:10 am  Welcome & Opening Remarks
Room: Salon F
Speaker: Andrew Fish, President & CEO, Medical Device Innovation Consortium

9:10 – 9:40 am  Fireside Chat with FDA commissioner
Room: Salon F
Speakers:
• Robert Califf, MD, Commissioner, FDA
• Jijo James, MD, MPH, Chief Medical Officer, MedTech & External Innovation, Johnson & Johnson

9:40 – 10:10 am  Fireside Chat with CMS Chief Medical Officer
Room: Salon F
Speakers:
• Lee Fleisher, MD, Chief Medical Officer and Director of the Centers for Medicare & Medicaid Services Center for Clinical Standards and Quality
• Nadim Yared, President & CEO, CVRx

Room: Salon F
Experts will examine how the digital health revolution is challenging the existing regulatory frameworks, including current regulatory barriers to adopting digital medical technologies, potential regulatory improvements, key considerations for patients and healthcare providers, and implications for the future of digital health innovation. Panelists will also discuss MDIC’s ongoing efforts in advancing digital health regulatory science.
Moderator: Yarmela Pavlovic, VP of Regulatory Strategy, Medtronic
Speakers:
• Brendan O’Leary, Acting Director, Division of Digital Health, FDA
• Anindita Saha, Assistant Director, Supervisor for Digital Health Center of Excellence, Division of Digital Health, FDA
• Amy McDonough, Managing Director & General Manager, Fitbit Health Solutions at Google
• Cassie Scherer, Senior Director of Digital Health Policy and Regulatory Strategy, Medtronic
• Heather Benz, Associate Director of Clinical Research for Robotics & Digital Solutions, Johnson & Johnson MedTech
11:05 – 11:20 am  Coffee Break  Room: Salon F

11:20 am – 12:15 pm  General Session 2 – NESTcc Quality Evidence by Design: Leveling up with Real-World Evidence  Room: Salon F
As NESTcc completes its last year of MDUFA IV funding and enters MDUFA V funding, we are building the national evaluation system based on our learnings from pilots and independent assessment. Learn how NESTcc is advancing the system architecture for scalability and interoperability to generate quality evidence by design.

Moderator: Richard Smith, MBA, Director of Business Development and Partnership, NESTcc

Speakers:
• Sandi Siami, MPH, Senior Vice President, NESTcc
• Diane Wurzburger, JD, Executive Regulatory Affairs and Quality, GE Healthcare
• Doug Fridsma, MD, PhD, Head of Government Partnerships, Datavant
• Christian Howell, Senior Vice President & General Manager, Medical Device and Diagnostic Group, Aetion
• Felipe Aguel, PhD, Deputy Director, Office of Clinical Evidence & Analysis, FDA

12:15 – 1:15 pm  Lunch  Room: Pennsylvania Avenue Terrace

1:15 – 2:10 pm  General Session 3 – Real World Evidence Benefiting Patients and Payers  Room: Salon F
Real-world evidence is becoming increasingly important for reimbursement decision making. Historically used for post-market safety monitoring, real-world evidence is now integrated throughout the product development lifecycle and has led to the real-time analysis of data to better understand and gain insights on disease, approaches to treatment, and how to achieve coverage decisions. Gain insights on how payer stakeholders are impacted by real-world data and real-world evidence; learn how to apply successful use cases, real-world examples, and practical outcomes into your own company; recognize how real-world data can be used to assist in study design and as a data source to facilitate device development, clinical trials, and evidence generation; and anticipate and plan for future requirements by CMS in the appropriate use of RWE in Coverage with Evidence Development

Moderator: Kimberly Sterling, PharmD, Vice President, Health Economics and Outcomes Research ResMed

Speakers:
• Lindsay Bockstedt, PhD, Vice President, Global Health Economics and Outcomes Research, Medtronic
• Daniel Caños, PhD, MPH, Director, Office of Clinical Evidence and Analysis, FDA
• Shelby Harrington, Principal, Quality and Clinical Strategy, Avalere Health
2:10 – 3:00 pm  
**CDRH Townhall**  
Room: Salon F  
**Moderator:** Jeffrey Shuren, MD, JD, Director, Center for Devices and Radiological Health, FDA  
**Speakers:**  
- Suzanne Schwartz, MD, Director, Office of Strategic Partnerships & Technology Innovation (OST), FDA  
- Michelle Tarver, MD, PhD, Deputy Director, Office of Strategic Partnerships & Technology Innovation (OST), FDA  
- Brendan O’Leary, Acting Director, Division of Digital Health, FDA  
- Daniel Caños, PhD, MPH, Director, Office of Clinical Evidence and Analysis, FDA  
- Edward Margerrison, PhD, Director, Office of Science & Engineering Laboratories, FDA  

3:00 – 3:15 pm  
**Coffee Break**  
Room: Salon F  
Presented by Compliance Group, Inc.  

3:15 – 4:00 pm  
**Concurrent Session 1**  
**Session A–Clinical Diagnostics: A Critical Path for Innovation and Precision Medicine**  
Room: Salon F  
Accurate and accessible diagnostics are the prerequisite for effective precision medicine. Representatives from FDA, NIST, MDIC, and industry will discuss approaches to an improved regulatory path for innovative diagnostics incorporating evolving technologies or targeting new diseases while ensuring accuracy in performance.  
**Moderator:** Maryellen de Mars, PhD, Program Director, Clinical Diagnostics, MDIC  
**Speakers:**  
- Brad Spring, Global Head of Regulatory Policy and Intelligence, Roche  
- Wendy Rubinstein, MD, PhD, Deputy Office Director for Personalized Medicine, Office of Health Technology 7 (In Vitro Diagnostics), FDA  
- Justin Zook, PhD, Co-Leader Biomarker and Genomic Sciences Group at National Institute of Standards and Technology (NIST)  
- Victor Sementchenko, PhD, Director of IVD Development, Illumina  

**Session B–Transforming Patient Engagement in MedTech**  
**Room: Hart**  
Learn how MDIC is expanding patient science in Total Product Life Cycle. Join our steering committee chair, Dan Stephens and MDIC’s Science of Patient Input team to learn more about our ongoing and new initiatives to accelerate patient engagement in Total Product Life Cycle. Interact with industry experts to explore innovative pathways for improving patient engagement and outcomes across the healthcare continuum. Share your input and insights in this small group concurrent session.  
**Speakers:**  
- Dan Stephens, Co-Chair SPI Steering Committee, Medical Device Innovation Consortium (MDIC)  
- Heidi Dohse, President, Founder, Tour de Heart; Patient Advocate  
- Maddie Gittens, Patient  
- Maria Gmitro, President & Founder, Breast Implant Safety Alliance  
- Greg Guinther, Patient  
- Erich Lin, Patient
4:05 – 4:50 pm
Concurrent Session 2
Session A–Computational Modeling and Simulation: Bringing Transformative Advancements to Healthcare
Room: Salon F

Experts across industries recognize that physics-driven and data-driven models complement each other and together can yield maximum insight into observed behavior while motivating future innovations. However, computer-based testing and generation of regulatory evidence for medical devices lag far behind similar efforts in other industries, such as aerospace, automotive, and nuclear energy. MDIC is collaborating with key stakeholders, including FDA, industry, academia, and international non-profit organizations to close this gap by creating the necessary frameworks, models, and simulation practices to support efficient use and regulatory evaluations. This session will focus on global developments, key considerations, and innovative ideas from government, regulatory, and industry experts in addressing the medical device industry’s needs.

Moderator: Randall Schiestl, Vice President, Research & Development, Global Technology, Boston Scientific

Speakers:
• Grace Peng, PhD, Program Director, Division of Discovery Science & Technology, Mathematical Modeling, Simulation and Analysis, National Institute of Biomedical Imaging and Bioengineering (NIBIB), National Institutes of Health (NIH)
• Edward Margerrison, PhD, Director, Office of Science & Engineering Laboratories, FDA
• Cheryl Liu, PhD, Senior Principal Engineer, Stryker
• Steven Levine, PhD, Senior Director, Virtual Human Modeling, Dassault Systèmes

Session B–Case for Quality: Envisioning a Formative MDIC Program
Room: Hart

Moderator: Todd West, Vice President of Membership & Development, Medical Device Innovation Consortium

MDIC’s Case for Quality Program looks to define how RWE/RWD, quality, and risks collide to shift the culture of quality across industry. The Case for Quality team will outline its visionary efforts and detail how innovation will bring value to the healthcare landscape. This impactful session will allow you to engage with thought leaders from industry, FDA, and MDIC in envisioning the Case for Quality at the next level.

Speakers:
• Steven Silverman, President, The Silverman Group
• Francisco Vicenty, Program Manager, Case for Quality, OPEQ, FDA
• Bleta Vuniqi, Policy Analyst, Case for Quality, OPEQ, FDA
• Sara A. Sulfridge, Senior Director Quality Strategy, Baxter
• Ravi Nabar, PhD, MBA, Senior Director Quality, Thermo Fisher
• Joseph Sapiente, Vice President of Clinical Science and Technology, Medical Device Innovation Consortium
Session C–What Outcomes Matter Most to Patients
Room: Russell

Patients have unique perspectives about the value of the potential benefits and the impact of potential harms and burdens of their medical treatments. While researchers, clinicians, medical device companies, regulators, payers, and HTAs play critical roles in evaluating the benefits and risks of medical products, only patients live with their medical conditions and make choices regarding their own care.

Moderator: Barry Liden, JD, Director of Public Policy, USC Schaeffer Center
Speakers:
• Keely Scamperle, MJ, FACHE, CPC, CCS-P, CHC, Vice President of Reimbursement and Market Access, Apollo Endosurgery
• Joe Nadglowski President & CEO, Obesity Action Coalition
• Juan Marcos Sepúlveda, PhD, Duke University

5:00 – 7:00 pm
Closing Reception
Room: Pennsylvania Avenue Terrace

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