MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

2020 in Review

Another year has come to an end and MDIC continues to strive for timely access to safe and cost effective medical innovations to improve patients' lives.

Listening to the needs of our stakeholders, we focused significant effort on providing patient and industry COVID-19 resources, establishing new project and focus areas, and putting patients at the center of our work.

In collaboration with our members, we also continued to create new regulatory science tools and foster collaboration among the medical device ecosystem through virtual forums, workshops, and webinars.

MDIC IN 2020

Putting Patients at the Center of Our Work

- First-ever **MDIC Patient Engagement Forum**, bringing together patients, patient groups, industry, investigators, providers, payers, and regulators to learn and share challenges and best practices for communicating with patients
- **Science of Patient Input (SPI) resources** to help manufacturers communicate with patients
- Collaboration between patients, patient advocates, and scientific experts to produce **a guide for patients considering medical procedures during the COVID-19 pandemic**
- Recognition by the Regulatory Affairs Professional Society (RAPS) with the **2020 Patient-Centered Health Award**

MDIC IN 2020

Creating a Forum for Meaningful Collaboration

- Workshop to **help IVD products under Emergency Use Authorization (EUA) advance to full marketing status**
- **Early Feasibility Study (EFS) budgeting best practices** and roundtable workshop with leading sponsors and sites
- Webinar on efforts to **help manufacturers improve performance and compliance** via the Accelerate Sustainable Capability (ASC) Pilot Study
- **First virtual Annual Public Forum** with more than 1,200 attendees and **headlined by FDA Commissioner Hahn**
- Two **Case for Quality Forums**
- Inaugural **Threat Modeling Bootcamp**
- Meeting to discuss the **role of real-world evidence (RWE) in coverage and payment decisions for devices and diagnostics**
- Recognition of **two new Collaborative Communities (CCs) with FDA participation:** Case for Quality Collaborative Community (CfQcc) and Pathology Innovation Collaborative Community (PIcc)

MDIC IN 2020

Developing New Tools and Resources to Help Innovate

Released:

- *Incorporating Patient Perspectives in Clinical Trial Design & Research White Paper*
- *Best Practices for Communicating Benefit, Risk, and Uncertainty for Medical Devices Report*
- *IVD Real-World Evidence Generation Framework*
- *Early Feasibility Study (EFS) Toolkit*

In Progress:

- *IVD Fingerstick Specimen Blueprint*
- *Case for Quality Leadership Engagement Playbook*
- *Patient Engagement in Clinical Trials: Patient, Industry, and Clinical Investigator Perspectives Report*

MDIC IN 2020

Leading Amidst Uncertainty

- **COVID-19 resource page** to offer novel coronavirus updates and resources to the industry
- **Discussion tool for patients** considering a medical procedure during the pandemic
- **Resources for SARS-CoV-2/COVID-19 laboratory test coding** via SHIELD
- **COVID-19 Real-World Evidence (RWE) project** bringing IVD manufacturers, FDA, and hospitals together to educate on practical RWE use
- **Quick pivot to virtual events,** including our two flagship events—the Annual Public Forum and Patient Engagement Forum—and many more

MDIC IN 2020

Addressing the Needs of the Ecosystem

- **New Efforts in 2020:**
  - CAPA Process Improvement Pilot Study
  - Accelerate Sustainable Capability (ASC) Pilot Study
  - SHIELD webpage with laboratory test coding resources
  - Industry Advisory Council for the ENRICHMENT *in silico* Clinical Trial Project
  - 5G-enabled Health Technologies Initiative
  - Advanced Manufacturing Initiative and Advanced Manufacturing Clearing House
  - Computer Software Assurance Alliance
- 2nd Annual Report to **quantify and demonstrate the organization's impact** and identify opportunities for growth and improvement