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Dear MDIC partners and stakeholders,

2021 was a year of transformations for MDIC. While we continue to focus on regulatory and safety science for patient benefit, MDIC now has a renewed mission and vision. We have transformed the way we think and speak about what we do and why we do it to better align with our desire to transform healthcare so that patients not only benefit but thrive:

“MDIC’s mission is to leverage its unique position as the only public-private partnership of its kind to transform health care into human care. Collaborating with our partners to advance science, we enable transformational medical technology to shape the world we want to live in and make that world possible by shortening the path from innovation to safety to access.”

Our work in 2021 reflected our desire to advance the use of real-world data (RWD) and real-world evidence (RWE) and to help transform regulatory science to keep up with the pace of digital health innovation. In advancing the use of RWD and RWE, we held a forum on RWE in payer decision-making, two National Evaluation System for health Technology Coordinating Center (NESTcc) forums on RWE and NESTcc’s 21 pilot projects (Test-Cases) on using RWE for regulatory decision-making, and an education series on designing in vitro diagnostic RWD studies.

The new Digital Health Initiative reflects the convergence of connectivity, information, and software with medical devices. It replaces the Data Science and Technology Initiative and works across all MDIC initiatives.

Also, we continued to put patients at the center of our work, provide a forum for meaningful collaboration, develop new tools and resources to facilitate innovation, and address the needs of the ecosystem. This Annual Report showcases our quantitative and qualitative accomplishments in 2021.

We would like to thank you for another year of your support and commitment to faster, safer, and more cost-effective innovation for patient benefit. Our accomplishments would not be possible without the hard work and expertise from our partners across industry, academia, government, healthcare systems, and patient advocacy groups. We look forward to our continued partnership with you.

Sincerely,
MDIC’S INITIATIVES AND PROGRAMS

MDIC improves the processes for development, assessment, and review of new medical devices through parent initiatives and related programs in four areas:

- CLINICAL SCIENCE
- DIGITAL HEALTH AND TECHNOLOGY
- HEALTH ECONOMICS AND PATIENT VALUE
- NATIONAL EVALUATION SYSTEM FOR HEALTH TECHNOLOGY COORDINATING CENTER (NESTcc)

Here we present the 2021 accomplishments of these initiatives and programs.
CLINICAL SCIENCE

The Clinical Science initiative addresses the biggest barriers to collecting adequate clinical evidence in support of new medical technology by:

- Creating blueprints for innovative clinical trial techniques
- Developing standards and metrics for effective clinical trial designs
- Encouraging the collection of adequate and appropriate clinical and patient preference data

PROGRAMS:

- Early Feasibility Studies
- Clinical Diagnostics
- Science of Patient Input

2021 CLINICAL SCIENCE YEAR IN REVIEW

EARLY FEASIBILITY STUDIES

The Early Feasibility Studies (EFS) program develops tools and best practices to help sponsors and clinical research sites improve the overall efficiency of EFS trials conducted in the U.S. The program also supports continuous assessment of EFS efficiency and effectiveness as new technologies are brought to U.S. patients in need.

Expansion into the Neurovascular Space

The EFS Program launched the Neurovascular EFS Initiative at the 2021 Annual Meeting of the Society of Neurovascular Interventional Surgeons, added members to the Neurovascular Steering Committee, and established two neurovascular Working Groups. The Neurovascular Steering Committee, co-chaired by Chip Hance, MBA, and Adnan Siddiqui, MD, PhD, includes representatives of industry, academia, and FDA. Hance is CEO of Regatta Medical and MDIC EFS Initiative Board Champion. Dr. Siddiqui is Professor of Neurosurgery at SUNY University at Buffalo and CEO of the Jacobs Institute. The neurovascular Working Groups are (1) updating the Master Clinical Trial Agreement and (2) redesigning the current Informed Consent Form Template for neurovascular clinical trials.

Addressing the Needs of the Ecosystem

The EFS Program expanded into two new therapeutic areas: neurovascular and electrophysiology.

Expansion into the Electrophysiology Space

The Electrophysiology EFS Steering Committee, chaired by Peter Weiss, MD, was also established in 2021. The steering committee is comprised of representatives of industry,
FDA, academic physicians, clinical trial administrators, and a patient advocate. Dr. Weiss is a cardiac electrophysiologist at Banner University of Arizona Medical Center Phoenix and an Assistant Professor at the University of Arizona College of Medicine.

**EFS Symposium**

The 2021 3D EFS MDIC Symposium: *What Makes EFS Different?* identified and discussed unique challenges of U.S.-based EFS, including indemnification, reimbursement, and patient recruitment. 3D Dartmouth Device Development Symposium and MDIC’s Clinical Science Initiative co-hosted the symposium.

**Email Newsletter**

EFS Express, an email newsletter, engaged and informed the EFS community with updates on the EFS program and success stories of three sponsors and three sites. Success stories highlighted the MDIC tool(s) used and how the sponsor or site used the tool(s) to improve the efficiency of EFS.

**New EFS Program Director**

MDIC welcomed Liz Mino, PhD, as Program Director of the EFS Program. Dr. Mino has 17 years of experience in the medical device industry, primarily in the start-up space. Before joining MDIC, Dr. Mino was a Principal Scientist for Acutus Medical, Inc. She has worked for several medical device manufacturers in the roles of clinical director, field clinical engineer, and field scientist. Dr. Mino has a PhD in applied physiology from the University of Utah and she completed a Post-Doctoral Fellowship at New Mexico Resonance.

**CLINICAL DIAGNOSTICS**

Providing a predictable path for innovation in clinical diagnostics gives patients quicker access to more advanced and cost-effective diagnostic technologies. The Clinical Diagnostics program works on projects to improve diagnostic testing and product development using novel regulatory science approaches developed through collaboration between MDIC stakeholders.

**Projects on Real-World Evidence**

MDIC conducted several projects to facilitate the use of RWE in regulatory submissions for in vitro diagnostics (IVDs).

**PROCESS FOR CONVERTING EMERGENCY USE AUTHORIZATION (EUA) COVID-19 IVDS TO FULL MARKETING STATUS**

The IVD RWE “Open Hand” project is a collaboration between MDIC, sponsors, and the FDA to advance the understanding of regulatory grade RWD and RWE. The collaboration focuses on requirements for converting COVID-19 diagnostics used under EUAs to full market approval using RWD and RWE. MDIC has developed the IVD RWE Education Series and is developing a manuscript based on lessons learned from this collaboration.

“I’m grateful for MDIC’s work to advance the EFS program as it provides innovative companies like Stereotaxis a clearer path to advance meaningful therapies to the patients we serve.”

—DAVID FISCHEL
CEO, Stereotaxis
Developing New Tools and Resources to Facilitate Innovation

The Clinical Diagnostics Program published a blueprint for analytical validity studies of point-of-care testing devices that use fingerstick specimens and developed the IVD RWE Education Series and a manuscript on the IVD RWE “Open Hand” project.

IVD Fingerstick Blueprint

*Study Design Blueprint for Evaluating Analytical Performance Characteristics of Point of Care In Vitro Diagnostic Devices with Capillary Whole Blood (Fingerstick) Specimens*, also known as the Fingerstick Blueprint, highlights design considerations for analytical validity studies of point of care testing devices that use fingerstick specimens including:

- Study designs for candidate device clearance/approval as a non-waived test
- Study designs for CLIA Waiver Application for the candidate device
- Minimum sample size requirements for study execution
- Use of surrogate samples
- Data analysis for method comparison and precision studies, and more

Cancer Somatic Reference Samples Project

The Somatic Reference Sample program focuses on developing reference samples that can be made available to the public to improve the accuracy, reliability, and transparency of next-generation sequencing-based oncology tests. MDIC presented the program during the 2021 Virtual Workshop on Next-Generation Sequencing and Radiomics: Resource Requirements for Acceleration of Clinical Applications, Including AI, hosted by the NIH and FDA Joint Leadership Council Next-Generation Sequencing and Radiomics Working Group.

MDIC received $3.5 million in external funding from the Gordon and Betty Moore Foundation, National Philanthropic Trust, Illumina, and Quidel for the Somatic Reference Samples Initiative pilot project. The project will engineer and validate reference samples containing 10 priority cancer mutations to improve development and expedite the regulatory process for next-generation sequencing-based IVD tests.

MDIC Surrogate Sample Framework Becomes Part of International Standard

MDIC’s *Surrogate Sample Framework* (2017) proposes uniform terminology and recommendations on where surrogate samples might be justifiably used in IVD validation studies to promote more efficient study design and reduce inefficient use of biological test materials.

In 2021, the Clinical and Laboratory Standards Institute incorporated MDIC’s *Surrogate Sample Framework* in its international standard EP39: A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests. The guideline establishes a definition, provides recommendations for when to use surrogate samples, and describes a process for selecting the most appropriate surrogate samples.
SCIENCE OF PATIENT INPUT

The Science of Patient Input program advances the art and science of patient engagement in the development, pre-market approval, and post-market evaluation of medical devices. Projects focus on incorporating the patient's perspective and preferences in devices.

Framework for Patient Input Published

MDIC completed the Framework for Incorporating Patient Input into Medical Device Clinical Trials, under a Broad Agency Announcement contract from the FDA. The Framework is designed to advance methods to integrate patient input into the design of clinical trials, advance a transformative method for integrating patient preferences into the statistical design of clinical trials, and synthesize practical considerations for reducing the patient burden of participation in clinical trials.

Putting Patients at the Center of Our Work

The Science of Patient Input Program published resources to help device manufacturers communicate with patients and maximize patient input.

Resources for Incorporating Patient Input

MDIC published reports to help device manufacturers understand and incorporate patient input into medical device development.

Maximizing Patient Input in the Design and Development of Medical Device Clinical Trials: A Report of the Science of Patient Input Program of the Medical Device Innovation Consortium provides a concise set of considerations for medical device developers to evaluate as they pursue patient engagement in their clinical trials and product development activities.
MDIC Patient Engagement Forum: Communicating Benefit, Risk & Uncertainty: November 2020 Forum: Lessons Learned report, summarized the key themes, topics, and lessons learned from the inaugural patient engagement forum. Report content included FDA’s commitment to patient centricity, the need to consider the cycle of a patient’s life instead of the total product life cycle, and the crucial role of providers.

Combined Survey Report: Patient Engagement in Clinical Trials: Patient, Industry, and Clinical Investigator Perspectives provides a detailed picture of how various stakeholders view challenges and opportunities with patient engagement in device development. The report also helps augment the evidence base for this work. Another report, Using Patient Preference Information in the Design of Clinical Trials (PPI-CT) Framework, was completed in 2021 and will be released in 2022.

Journal Articles and Literature Review


A manuscript from the Heart Failure Project, "Quantifying Benefit-Risk Preferences for Heart Failure Devices: A Stated-Preference Study," was accepted for publication in 2021 in Circulation: Heart Failure (and subsequently published in January 2022).

The updated high-level Literature Review: Patient Engagement in Clinical Trials is a broad scan of publicly available information about relevant organizations, initiatives, materials, and publications.

Two other manuscripts were completed and will be submitted for publication:

- The Bayesian decision analysis tool: Patient-Centered Clinical Trial Design for Heart Failure Devices via Bayesian Decision Analysis
- Manuscript version of the report Patient Preference Information in the Clinical Trials Framework: Leveraging Patient Preference Information in Medical Device Clinical Trial Design

Updated Patient Discussion Tool

MDIC updated its Discussion guide for patients considering a medical procedure during COVID-19 for patient use in talking to healthcare providers. Patients, patient advocates, and medical and scientific experts collaborated on the patient discussion tool. The web page featuring the guide also has links to other patient resources about COVID-19.

New Working Group on Digital Health

The new Digital Health in the Science of Patient Input Working Group will develop a digital health survey to identify and highlight successes, challenges, and opportunities in digital health tools over the healthcare continuum.

“I’m excited that things I have been doing to engage patients are moving forward.”

—PATIENT ADVOCATE PARTICIPANT
DIGITAL HEALTH AND TECHNOLOGY

Launched in 2021, the Digital Health and Technology Initiative represents the evolution of MDIC’s Data Science and Technology Initiative to help transform regulatory science to keep up with the pace of digital health innovation. Digital Health and Technology replaces the Data Science and Technology Initiative and works across all MDIC initiatives.

The Digital Health and Technology Initiative recognizes the convergence of connectivity, information, and software with medical device development and provides an opportunity to focus on software as a medical device, software in a medical device, mobile medical applications, interoperability, wireless medical devices, patient-generated health data, and in-silico validation/modeling. It includes all of the MDIC programs that were previously part of the Data Science and Technology Initiative.

PROGRAMS:

- Digital Health
- Case for Quality Collaborative Community
- Cybersecurity
- Medical Extended Reality Devices
- Computational Modeling and Simulation
- External Evidence Methods
- 5G-Enabled Health Technologies
- Artificial Intelligence and Machine Learning for In Vitro Diagnostics
- Pathology Innovation Collaborative Community
- Systemic Harmonization and Interoperability Enhancement for Lab Data (SHIELD)
- Computer Software Assurance Alliance

2021 DIGITAL HEALTH AND TECHNOLOGY YEAR IN REVIEW

Transforming Regulatory Science for Digital Health Innovation

The new Digital Health and Technology Initiative and Digital Health Program recognize the convergence of connectivity, information, and software with medical device development.

DIGITAL HEALTH

Launched in 2021, the Digital Health (Software) Program will complement FDA’s efforts to develop an innovative regulatory pathway for software that is tailored to its unique and iterative nature, including leveraging the learnings from the FDA pre-certification pilot program.

Through five initial workstreams, the Digital Health Program is focusing on regulatory science for software in medical devices and software as medical devices:

- Change Control
- Excellence Appraisal
- Review Determination
- Streamlined Premarket Review
As digital health technologies are increasingly becoming an integral part of medical devices, I am excited to see that MDIC is launching this new initiative which is well poised and will drive synergy and advance this field.

— BAKUL PATEL
Former Director, FDA Digital Health Center of Excellence

- Evidence Generation, including RWD collection and use of RWE such as patient-generated data and computer modeling and simulation.

**Webinar on Digital Health**

In July 2021, MDIC hosted a webinar to discuss the existing regulatory framework for digital health, key considerations for patients and healthcare providers, and implications for the future of digital health innovation. The panel of experts, which included Bakul Patel, former Chief Digital Health Officer at FDA; Eric Friedman, Founder and CTO of Fitbit (a consumer electronics and fitness company focusing on wearables); Cassie Scherer, Director of global regulatory policy at Medtronic (a medical device manufacturer); and Heidi Dohse (a patient/patient advocate and Founder of Tour de Heart), brainstormed on how to collaborate to advance regulatory science related to digital health.

**CASE FOR QUALITY COLLABORATIVE COMMUNITY**

The Case for Quality Collaborative Community brings together the FDA and other medical device stakeholders to enhance device quality and patient safety through recognition and support of best practices for consistent quality manufacturing. This program allows the FDA to identify high-quality device manufacturers and allocate its resources to assist other device manufacturers in increasing their quality.

**Voluntary Improvement Program**

In 2021, MDIC transitioned the Voluntary Improvement Program from a pilot to a full program, and the FDA began to develop a complementary permanent program based on the lessons learned from their engagement in the pilot program. Conducted in collaboration with the Center for Devices and Radiological Health (CDRH), the Voluntary Improvement Program empowers stakeholders across the medical device ecosystem to improve quality and patient outcomes. Participating manufacturers provide supplementary data to the FDA, which can help simplify the review process.

MDIC also re-launched the Voluntary Improvement Program working groups.

**CAPA Process Improvement Pilot Study**

The CAPA (Corrective and Preventive Action) Process Improvement Pilot Study sought to recast the CAPA process as a continuous improvement process and make it less burdensome while also driving higher product quality. Based on an MDIC white paper on CAPA process improvement, the pilot study enrolled more than 20 device manufacturers. In 2021, MDIC completed the pilot study and drafted the second white paper on CAPA process improvement.
Addressing the Needs of the Ecosystem through Pilot Studies

The Case for Quality Collaborative Community is conducting pilot studies on voluntary improvements in quality and patient outcomes, improving performance and compliance, and information sharing.

Accelerate Sustainable Capability (ASC) Pilot Study

Designed to help device manufacturers improve performance and compliance, the Accelerate Sustainable Capability (ASC) Pilot Study was launched in 2020. Developed in collaboration with the medical device industry, the Information Systems Audit and Control Association, and FDA, the pilot study is open to device manufacturers that:

- Self-identify major deficiencies with the Quality System regulation
- Received an FDA Form 483 during a recent inspection
- Received an FDA advisory action.

In 2021, five device manufacturers enrolled in the study, for a total of nine participating device manufacturers. All of the device manufacturers began their appraisals.

Medical Device Information and Sharing (MDIAS) Project

The MDIAS project focuses on improving healthcare outcomes by building a data-sharing collaboration to analyze and share medical device data from various public and non-public sources. An independent, trusted third party will collect and analyze these data, which can be used to identify trends in and provide insights on device quality and safety. In 2021, MDIC completed a MDIAS pilot study and the proof of concept for the Safe Space pilot. Safe Space is a non-competitive, collaborative, and sanction-free environment for open discussions on quality improvement in data sharing.

Advanced Manufacturing Landscape Analysis

In 2021, MDIC published the *Advanced Manufacturing Landscape Analysis* white paper, which describes advanced manufacturing and its benefits, and highlights roadblocks to achieving advanced manufacturing and how to navigate around them. The white paper reviews the current state of the medical device industry and compares it to other industries, leveraging experiences and lessons learned. Also, the white paper provides a flexible path for moving toward advanced manufacturing.

Case for Quality Forums and Annual Public Forum Presentations

MDIC provided updates on the activities of the Case for Quality Collaborative Community through two Case for Quality forums and two presentations at the MDIC Annual Public Forum.

Culture of Quality Leadership Engagement Events

In 2021, MDIC held three events to facilitate a culture of quality based on the *Leadership Engagement Playbook*, which highlights best practices and tools to help leaders move their companies from a culture of compliance to a culture of quality. The two forums included sessions on quality culture and quality strategy, and the webinar focused on the cost of quality.
Member Engagement Roundtable
MDIC held a membership engagement roundtable discussion with leaders from small and medium-size device firms. The goal of the roundtable was to obtain input on the activities of the Case for Quality Collaborative Community.

CYBERSECURITY
Device manufacturers must address cybersecurity as part of their ongoing efforts to ensure the safety and effectiveness of medical devices across their lifecycle. MDIC’s Cybersecurity Program focuses on identifying priorities to help the medical device industry ensure device safety and effectiveness.

Threat Modeling Bootcamps and Playbook
Threat modeling provides a blueprint to strengthen security through the total product lifecycle of medical devices. To increase adoption of threat modeling throughout the medical device ecosystem, FDA engaged MDIC, the MITRE Corporation, and Shostack & Associates to conduct threat modeling bootcamps in 2021 as well as a Train-the-Trainers workshop. Based on the overwhelming demand for the threat modeling bootcamps, MDIC plans to hold additional bootcamps.

In 2021, MDIC and MITRE published the *Playbook for Threat Modeling Medical Devices*, which was developed by the same team based on the learnings from the bootcamps to further increase the outreach and adoption of threat modeling best practices for medical devices. The playbook focuses on general threat modeling principles and can be used as a resource for threat modeling training within an organization.

MedTech Industry Benchmarking
MDIC launched the MedTech Cybersecurity Maturity Benchmarking Initiative in 2021. This initiative is built on the MedTech Joint Security Plan (JSP Framework) developed by the Health Sector Coordinating Council. The JSP Framework addresses cybersecurity challenges and is helpful in establishing cybersecurity capabilities such as security design requirements, risk assessment, testing, vulnerability disclosures, and customer security documentation.

Working with medical device manufacturers, MDIC has developed a common method and rubric (a benchmark) for measuring cybersecurity maturity across the medical technology industry. The goal is to drive common improvements that reduce the overall cybersecurity risk.

The benchmark is based on insights from the anonymous Medical Device Cybersecurity Maturity Survey, which medical device manufacturers of various sizes can also use to:

- Better understand and measure their product security programs
- Further adopt secure product development framework
- Build more robust, higher-quality, medical devices that positively impact public health

The threat modeling bootcamps and the first-of-its-kind playbook apply scientific methods of threat modeling, leading to safer, more resilient medical devices that improve patient lives.

— SUZANNE SCHWARTZ, MD, MBA
Director, Office of Strategic Partnerships & Technology Innovation
FDA Center for Devices and Radiological Health
Companies that use this free online survey tool developed by MDIC can receive a high-level report containing the company’s individual score as well as their product security posture relative to industry peers.

Transforming Regulatory Science for Digital Health Innovation

The Cybersecurity Program is identifying best practices in cybersecurity that device manufacturers can replicate to ensure patient safety and security.

Medical Device Penetration Testing

Penetration testing is a best practice for software-based devices that manage sensitive data or provide diagnostics or therapies for patients. In 2021, MDIC launched the Cybersecurity Penetration Testing project to examine best practices and make recommendations on how this technique best fits in a regulated medical device environment. MDIC completed the first in a series of white papers, *Penetration Testing as a Medical Device Verification & Validation (V&V) Process*.

MEDICAL EXTENDED REALITY (MXR) DEVICES

Medical extended reality, which includes augmented reality and virtual reality, is an emerging and rapidly changing field that may improve efficiency and outcomes in surgery and interventional procedures, diagnostics, and therapeutics. But the rules for evaluating these technologies from the benefit-risk and outcomes perspectives are still in the nascent stage.

Launched in 2021, the Medical Extended Reality Devices Program will develop a roadmap for implementing augmented and virtual reality. It will identify open evaluation challenges and knowledge gaps that impede the development and implementation of, and regulatory process for, novel applications of MXR devices across healthcare applications and engage in collaborative activities to address those challenges.

The initial focus is to develop a framework for image quality, human factors, and training to support the safety and effectiveness of 3D-capable medical extended reality devices for surgical planning and procedures, including open and minimally invasive surgery. There are four working groups under the MXR program:

- The Training and Education Subgroup will develop approaches to demonstrate training
effectiveness and identify the most pressing gaps or challenges related to training.

- The Human Factors Subgroup will complete a landscape and gap analysis of human factors considerations for MXR devices for surgical planning and procedures. This workgroup will also identify relevant testing approaches, such as current standards documents.
- The Terminology and Taxonomy Subgroup will document standard terminology and definitions for MXR applications relevant to the framework.
- The Image Quality Subgroup will conduct a landscape and gap analysis of image quality and visualization accuracy considerations and testing for MXR devices for surgical planning and procedures.

### Transforming Regulatory Science for Digital Health Innovation

The Medical Extended Reality Program is currently working on a framework to identify considerations in assessing the safety and effectiveness of MXR devices for surgical planning and procedures.

### Computational Modeling and Simulation

Computational modeling and simulation can facilitate the development of safe and effective medical device technology in a responsible way that balances the desire for certainty in device performance with a limited delay in patient access. MDIC’s Computational Modeling and Simulation (CM&S) program explores ways to use computer modeling and simulation as valid scientific evidence for medical devices, with a focus on validation requirements for demonstrating regulatory-grade simulation results.

#### 5-Year Strategic Planning Landscape Study

MDIC completed the Computational Modeling and Simulation Program’s 5-Year Strategic Planning Landscape survey. Forty-two organizations, including from industry, government, and the nonprofit sector, participated in the survey.

Results from the landscape survey will be used to revise the 5-year strategic roadmap for the Computational Modeling and Simulation Program. The roadmap will chart the course of milestones to realize the vision of quick and predictable access for patients to innovative, safe, and effective technologies enabled by evidence from computer modeling and simulation.

#### Computer Modeling and Simulation as a Regulatory Tool

MDIC established a new working relationship with Avicenna Alliance, based in the European Union, to work on computer modeling and simulation during the medical device total product lifecycle. Avicenna Alliance is a nonprofit association of industry, academia, and healthcare organizations that have a commercial or research interest in the development, adoption, and deployment of in silico medicine to ensure safe, affordable, and cost-efficient healthcare. Working with Avicenna Alliance and other stakeholders, including FDA, industry, and academia, MDIC plans to transform computer modeling and simulation from a valuable scientific tool to a valuable regulatory tool and to develop mechanisms to leverage digital evidence globally.
EXTERNAL EVIDENCE METHODS

MDIC’s External Evidence Methods (EEM) program aims to assist stakeholders with the use of EEM, such as new, innovative, and existing statistical methods for evidence fusion from data external to a clinical study. Examples of external data include RWD, RWE, data from modeling and simulation, and clinical trial data from similar devices.

The purpose of incorporating external data is often to create efficiency in medical product development and regulatory decision-making, thereby bringing new, safe, and effective technologies to market sooner to help patients in need. External data may also provide insights into the clinical performance of the diagnostic device being studied. They can potentially be used in regulatory decision-making throughout the total product life cycle.

Medical device cybersecurity is essential to protecting not just data and systems, but also patient safety and privacy in a wide variety of care settings—from hospitals to patients’ homes. The MDIC’s efforts to establish a benchmark of the industry’s cybersecurity maturity provides an opportunity for all medical device manufacturers to assess their progress on the journey toward improving cybersecurity and resilience.

—ROB SUÁREZ, HCISPP
VP, Chief Information Security Officer for BD
Chair of the MDIC Cybersecurity Working Group

External Evidence Methods Framework

In 2021, MDIC released the draft *External Evidence Methods Framework*, a practical guide to navigating through the nuts and bolts of leveraging external data. Developed in collaboration with biostatisticians from FDA and industry, the Framework catalogs different sources of external data and statistical methods that can be used for generating external evidence, outlines considerations for using external data for regulatory decision-making, and provides examples of past studies in which external data supported the approval or clearance of medical devices or expanded indications.

5G-ENABLED HEALTH TECHNOLOGIES

5G networks will change the conduct of medical evaluation and treatment, creating both opportunities and challenges for device research, development, manufacturing, and assessment. The 5G-Enabled Health Technologies project will facilitate the future development of novel medical device technology based on 5G networks while ensuring patient safety.

Two Working Groups

In 2021, MDIC established two Working Groups under the 5G-Enabled Health Technologies project:

- The Landscape Analysis Working Group will review existing and potential uses of 5G in healthcare, identify knowledge gaps, and outline existing or needed evaluation methods.
- The Education Working Group will provide educational materials to the broader healthcare community through webinars, playbooks, and white papers.
ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING FOR IN VITRO DIAGNOSTICS

In collaboration with the Clinical Diagnostics Program, this program began work on Artificial Intelligence and Machine Learning (AI/ML) for In Vitro Diagnostics (IVDs), a framework for addressing iterative improvements in AI/ML-enabled IVDs, including IVDs, so that they maintain their safety and effectiveness. MDIC, FDA CDRH, and industry are working together on the IVD AI/ML framework, which focuses on issues and considerations in planning and implementing iterative changes in AI/ML algorithms, including those in software as a medical device and software in a medical device. The framework will include a glossary and templates for software pre-specifications and algorithm change protocols.

ADDITIONAL PROGRAMS

In 2021, MDIC continued development of several additional programs under Digital Health and Technology:

- The Pathology Innovation Collaborative Community is a regulatory science initiative that aims to modernize the clinical practice of pathology by facilitating innovations in digital pathology, advancing evaluation of safety and effectiveness, and harmonizing approaches.
- The Systematic Harmonization and Interoperability Enhancement for Lab Data (SHIELD) project focuses on developing publicly available infrastructure to improve the quality, interoperability, and portability of laboratory data within and between institutions to enable cross-institutional laboratory data interoperability.
- The Computer Software Assurance Alliance supports and engages with the FDA-Industry Computer Software Assurance team and applies critical thinking for assessing the risks of the computer software for patient safety and product quality and drive a streamlined and effective test assurance strategy.

“To improve patient care, we need to apply the best possible science as an input into regulatory activities. Many experts have recognized this tremendous opportunity and contributed to create this community.”

— JOE LENNERZ, MD, PHD
Medical Director, Center for Integrated Diagnostics, Massachusetts General Hospital Associate Professor, Harvard Medical School
HEALTH ECONOMICS AND PATIENT VALUE

The Health Economics and Patient Value (HEPV) initiative focuses on accelerating patient access to safe medical devices and amplifying the patient voice in treatment options. HEPV:

- Creates predictable and transparent evidence requirements for coverage
- Improves pathways for coverage, coding, and payment

2021 HEALTH ECONOMICS AND PATIENT VALUE YEAR IN REVIEW

The two HEPV working groups facilitate projects in (1) RWE and (2) patient perspective research to provide guidance on evidence requirements that would be a resource for payers.

Forum on RWE and Payer Decision-Making

More than 200 participants attended the virtual public forum on RWE in the context of payer decision-making hosted by MDIC and FDA. The forum covered:

- Examples of RWE used by FDA in regulatory decisions
- The perspective of CMS and other stakeholders on RWE
- Examples of the use and possible use of RWE in the development of medical technology

Workshop on Patient Preference Information in Coverage Decisions

MDIC sponsored a series of workshops with payers and health technology assessment organizations in 2021. The workshops focused on helping participants understand the benefits of patient preference information and explored the potential value from and perceived barriers to integrating patient preference information into U.S. medical device coverage decisions.

Landscape Assessment

HEPV completed an RWE landscape assessment to understand the use of RWE by payers to inform their medical device decisions and by health technology assessment organizations that influence these coverage decisions. The landscape analysis also included recommendations to these and other stakeholders for advancing the use of RWE to inform coverage of devices.

By sharing knowledge and leveraging resources, MDIC has played an important role in supporting medical device safety and innovation. CDRH remains committed to our continued partnership with MDIC and identifying opportunities to enhance our work together.

—JEFF SHUREN, MD, JD
Director Center for Disease & Radiological Health, Food & Drug Administration
NEW MISSION AND VISION

In 2021, NESTcc adopted a new mission and vision to guide its work:

Mission

The NESTcc community is passionately committed to transforming the way medical device technologies are tested, approved, and monitored.

Vision

We envision a world in which people are empowered to make informed medical choices that enable patients to live their lives to the fullest extent possible.

EVIDENCE GENERATION

16 Test-Cases Completed

NESTcc’s Test-Cases systematically assess the potential for medical device ecosystem stakeholders to work with RWD to support regulatory decision-making. They are also designed to identify areas where NESTcc could play a role in creating efficiencies in generating RWE. In 2021, 10 Test-Case projects achieved final results, bringing the total to 16 out of 21 Test-Cases completed.

Also, MDIC began building the system for NEST 2.0 based on learnings and experience from the first Test-Cases.

Disseminating Learnings on RWD and RWE

NESTcc published an interim report from the RAND independent assessment of the Test-Cases and hosted two forums on advances in and practical uses of RWD based on real-world experiences generating RWE.
**Interim Report on RAND’s NESTcc Test-Cases**

NESTcc contracted with the RAND Corporation (RAND) to conduct an independent assessment of NESTcc’s 21 Test-Cases. In 2021, NESTcc and RAND published an interim report on the 14 Test-Cases completed through August 2021. *Using Real-World Evidence to Support Regulatory Decisionmaking for Medical Devices: Interim Report on Lessons from the National Evaluation System for Health Technology Coordinating Center (NESTcc) Test-Cases* provides an overview of the Test-Cases, key lessons, and stakeholder views of the evidence based on interviews with submitting organizations, Network Collaborators, and FDA representatives.

**RWE Forums**

Through two virtual events—the NEST RWE Forum in May and RWE² in September—NESTcc highlighted findings from its completed Test-Cases. Both events focused on the latest advances in and practical uses of RWE, presentations on Test-Cases, and perspectives on the future use of RWE. More than 500 leaders from across the medical device ecosystem participated.

**RWE Publications**

Also, NESTcc Test-Case teams published three manuscripts in scientific journals:

- **Feasibility of using real-world data in the evaluation of cardiac ablation catheters: a test-case of the National Evaluation System for Health Technology Coordinating Center, BMJ Journal of Surgery Intervention and Health Technology.** 2021 Dec 9;3(1).

- **Feasibility of capturing real-world data from health information technology systems at multiple centers to assess cardiac ablation device outcomes: A fit-for-purpose informatics analysis report, Journal of the American Medical Informatics Association.** 2021 Sep 18;28(10):2241-2250.

- **Heart Watch Study: protocol for a pragmatic randomised controlled trial, BMJ Open 2021;11:e054550. doi: 10.1136/bmjopen-2021-054550.**

**Sponsored Projects**

NESTcc contracted its first sponsored premarket evidence generation projects as part of its plan towards self-sustainability. The projects reflect NESTcc’s ability to use diverse sources of data to address the RWE needs of large and small enterprises across the total product life cycle.

**Two New Network Collaborators**

NESTcc added two new Network Collaborators to the NESTcc Research Network: Regenstrief Institute and MedStar Health. Regenstrief Institute is a global leader in healthcare with 117 hospitals and 18,000 practices. MedStar Health Research Institute is the executive research organization for MedStar Health, which has 10 hospitals and 300 service centers.

**ACTIVE SURVEILLANCE**

**The NESTcc Active Surveillance System**

With funding from FDA, NESTcc is establishing a medical device active surveillance system to conduct timely, software-based RWD analysis of medical devices to identify and refine safety signals for postmarket monitoring. NESTcc is building a cloud-based infrastructure using federated analytics to collect and analyze RWD for medical device safety signal detection and assessment. In 2021, NESTcc finalized Phase I of this work and began Phase II.

**Active Surveillance Roadmap**

NESTcc released the draft *Active Surveillance Roadmap* for public comment. The roadmap summarizes progress made to date and describes forward-looking plans and activities needed to develop NESTcc’s active surveillance capabilities.
It details the technical characteristics of a cloud-based, federated learning environment to perform safety signal refinement and signal detection using RWD via a planned data network and describes planned research methods and procedures to ensure data quality along with guiding principles around signal management and communications to ensure that active surveillance capabilities are scalable, secure, and equitable to all stakeholders.

**Working Groups**

In 2021, NESTcc established the Active Surveillance Data Curation Working Group and expanded the IT Cloud Working Group. The Active Surveillance Data Curation Working Group provides expert recommendations on the adoption and extension of a Common Data Model and the creation of a data curation pipeline on medical devices for RWD used in general research and active surveillance. The IT Cloud Working Group is designing and building the active surveillance cloud infrastructure platform that will be used to facilitate the collection and analysis of RWD for medical device safety signal detection and assessment.

**NESTcc COLLABORATIVE COMMUNITY**

**Device Identification and RWD Meeting**

The second NESTcc Collaborative Community annual meeting focused on device identification and RWD. In a Think Tank format, leaders in the medical device ecosystem provided information, advice, and ideas on short- and long-term goals for device identification and how to leverage device identification in the generation of RWE. The annual meeting also included an overview of the FDA’s perspective on unique device identifiers (UDI) and an update on NESTcc’s study on the Evaluation and Uptake of UDIs by Health Systems.

**Creating a Forum for Meaningful Collaboration**

The NESTcc Collaborative Community annual meeting brought together stakeholders across the medical device ecosystem to discuss and generate ideas on RWD and device identification.

**UDI Center**

In 2021, NESTcc launched the UDI Center on its website. The UDI Center describes UDIs, the Global Unique Device Identification Database, and benefits of UDIs. It highlights national policy and initiatives related to UDIs. Also, the UDI Center lists clinical registries that accept UDIs and research databases with UDIs and provides links to publications and other useful content related to UDIs.
ANNUAL PUBLIC FORUM

The Annual Public Forum brings together MDIC members and the broader medical device and diagnostics community to discuss current trends in regulatory science and highlight the development of innovative regulatory science tools.

Headlined by a fireside chat with Acting FDA Commissioner Janet Woodcock, MD, the virtual Annual Public Forum drew 470 attendees. Other sessions covered topics such as:

- Clinical Diagnostics Fingerstick Blueprint
- Standards for real-world evidence
- Patient perspectives
- Medical device cybersecurity
- MDIC’s collaborative communities
- CDRH and CMS Town Halls

The excitement and pride generated during the Case for Quality Voluntary Improvement Program appraisals is tangible. These appraisals are truly helping our teams identify strengths, weaknesses and opportunities for improvement by engaging those most involved in our day-to-day work. Our teams remain focused throughout the year on applying feedback from the appraisals on-site and implementing global improvements in order to enhance the quality of service we deliver to our Customers around the world. The Case for Quality program has genuinely advanced not only our culture, associates and processes, but is also advancing the STERIS Mission to HELP OUR CUSTOMERS CREATE A HEALTHIER AND SAFER WORLD.

—LINDSEY MCGOWAN
Vice President, AST Quality Operations, STERIS Corporation
MDIC’s initiatives and programs also held information sessions, forums, workshops, and other events.

**OTHER MDIC EVENTS**

- PLAYBOOK FOR THREAT MODELING MEDICAL DEVICES WEBINAR: 1,440
- EXTERNAL EVIDENCE METHODS FRAMEWORK WEBINAR: 159
- FINGERSTICK BLUEPRINT WEBINAR: 169
- THREAT MODELING BOOTCAMP: 123
- CASE FOR QUALITY FORUM (APRIL): 168
- CASE FOR QUALITY FORUM (DECEMBER): 233
- INNOVATION AND INTEGRATION OF DIGITAL TECHNOLOGIES TO HEALTHCARE: ADVANCING REGULATORY SCIENCE THROUGH COLLABORATION WEBINAR: 424
- EFS SYMPOSIUM: 248
- HEPV REAL-WORLD EVIDENCE FORUM: 302
- RWE FORUM: 307
- NESTcc RWE²: 318
MDIC members are leaders in the medical technology industry. MDIC focuses on providing patients with access to innovative medical technologies so many of our members are companies that can help us do this. Member organizations are substantially involved in:

- Medical and/or medical device research, development, treatment, or education
- Promotion of public health, or
- Regulatory science.
INCOME

- Grant Revenue: 68%
- Membership: 16%
- Project: 1%
- Corporate Contributions: 11%
- Other: 4%

EXPENSES

- Operations/Management: 47%
- Rent/Facilities: 4%
- Meetings/Events/Other: 1%
- Project: 48%
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