Creating a Space for Innovative Device Development

Michelle McMurry-Heath* and Margaret A. Hamburg‡

The FDA announces a partnership with a new nonprofit organization—the Medical Device Innovation Consortium—to advance regulatory science in the medical technology arena.

The $136 billion medical device sector is critical to the nation’s health, providing products for 48 million domestic inpatient procedures every year (Table 1). Although this sector is best known for surgical instruments, cardiology devices, and orthopedic implants, it also includes all of the diagnostic tests and imaging equipment currently used to pinpoint disease and the burgeoning field of companion diagnostics, which are needed to fulfill the promise of personalized medicine (1).

Despite the extraordinary importance of devices to human health, there has been no concentrated effort to pursue precompetitive medical device research, which could bring broad benefits to medical device development and review. Efforts by either the public or private sector to support research that adequately targets the early product development stage of translation have been limited. For example, there are striking shortfalls in applied research in areas such as health-related engineering and regulatory science, which comprises the development of new tools, standards, and approaches to assess a product’s safety, efficacy, quality, and performance (Fig. 1). To address this translational gap, the U.S. Food and Drug Administration (FDA) is pleased to partner with a new nonprofit organization—the Medical Device Innovation Consortium (MDIC)—to foster regulatory science breakthroughs in the medical technology space with the ultimate goal of improving human health.

FDA and LifeScience Alley (LSA; https://www.lifesciencealley.org)—a biomedical science trade association—have worked together to develop the first medical device public-private partnership (PPP) whose sole objective is to advance the entire spectrum of regulatory science in this sector. MDIC will facilitate this ground-breaking collaboration among federal agencies, nonprofit organizations, industry, academic institutions, and other trade associations such as MassMedic (www.massmedic.com) and the California Healthcare Institute (www.chi.org). This PPP creates a safe space designed to encourage members to leverage their resources by focusing jointly on precompetitive (2) early-stage technology development efforts that otherwise would not take place because of the organizational structure of the device sector. Although there are large multinational device companies, most of the companies in this sector are much smaller than those in the pharmaceutical space. About 75% of the more than 5,000 device manufacturers in the United States are small companies with fewer than 20 employees (3). Start-up device companies have limited capital, and a start-up’s future often depends on the success of one complex device. Advances in regulatory science would speed the translation of these next-generation technologies. However, much of the sector lacks the resources to support regulatory science research, as well as mechanisms for working together to pool their resources to solve scientific issues.

MDIC members will make it a priority to develop regulatory methods and tools that can be adopted by the medical device community and will provide a forum for medical device stakeholders to securely share proprietary precompetitive data. Each advance achieved by medical device stakeholders through the sharing and leveraging of resources will assist industry in developing new

Fig. 1. Modern family. MDIC will facilitate collaboration among federal agencies, industry, and nonprofit groups to spur innovation in regulatory science for the development of complex interdisciplinary devices. Shown are funding sources (blue boxes) for the various stages of medical device discovery and development (white boxes) [adapted from (7)]. Regulatory science is part of early-stage technology development (shown in center of the pathway as a tri-colored box). This crucial step is not funded by traditional sources and will be the focus of MDIC. Solid white arrows, source frequently funds this technological stage; segmented white arrows, source occasionally funds this technological stage. SBIR, small business innovation research grants.

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products so that safe and effective medical devices can be brought to market at a faster rate. FDA invites all professionals interested in advancing medical technology to partner with FDA and MDIC in this effort.

**GOALS OF PARTNERING WITH MDIC**

MDIC was designed with flexibility in mind, so that it can adapt to the most pressing needs of patients and of the device industry as they evolve over time. In keeping with the goal of stakeholder engagement, MDIC is currently recruiting founding members who will work jointly with FDA to determine research priorities for the endeavor. Much like other successful PPPs in the pharmaceutical space, such as the Foundation for NIH or Critical Path Institute, the founding members will be asked to represent their stakeholder communities in (i) suggesting the most promising areas for research collaboration, (ii) raising funds to support these areas of investigation, and then (iii) issuing requests for grant proposals. Researchers and engineers from all sectors—industry, government, academia, or nonprofit organizations—will be encouraged to apply, and preference will be given to research consortia that cross sectors and take interdisciplinary approaches to problems. MDIC strives to support science conducted by research teams that have innovative ideas for the development of tools and methods for medical device design, testing, and regulatory approval.

Many fields of research within medical device regulatory science could potentially benefit from MDIC. An example that highlights MDIC’s potential to improve patient care is computational modeling and simulation of human pathophysiology, which can be used to augment in vitro and animal disease models in the preclinical stages of device development. The FDA’s Center for Devices and Radiological Health (CDRH) expects computational modeling to accelerate and streamline the regulatory review process but first needs to develop a strategy for assessing the technology’s credibility—its usefulness, quality, and reproducibility. CDRH has begun to develop a technological framework called the Virtual Physiological Patient (VPP), which, once completed, will provide a model for the human body as a single complex system. However, cross-sector research teams are required to develop the normal and diseased reference models that will serve as benchmarks for device performance and safety. Using computational modeling and simulation, device designs can potentially be refined even before they enter clinical trials, improving safety for patients and reducing the cost of device development for companies.

Research on genetic testing could also benefit from MDIC-stimulated collaboration. Knowledge about a patient’s genetic makeup is critical for the successful treatment of many types of disorders (1). Although scientists have generated a wealth of data about genetic variations in human subjects, there are few concerted efforts to curate and organize this knowledge in a way that can support its clinical use. The FDA believes that a central, comprehensive, and expertly curated database of clinically meaningful genetic variations would be an invaluable source of data to support the development and marketing of clinically valid genomics-based products that would allow health care providers to take advantage of the best available science in managing the health of their patients.

Another emerging research area is medical device interoperability—the ability of devices that seamlessly operate with other medical devices and information systems (5). The MDIC could establish a framework to identify gaps in the interoperability field, prioritize the gaps, and then fund research accordingly. The MDIC also could help prioritize the development of standards for innovative interoperable medical devices and build test beds for these technologies. This research will help to ensure that interoperability issues do not pose a hazard to patients.

With the emergence of new materials in medical devices, FDA must develop updated biocompatibility standards based on the most recent scientific advances. The MDIC could support the development of new preclinical biocompatibility assays that predict potential adverse health responses in people exposed to biomaterials or nanoparticles (6).

**INNOVATION INFRASTRUCTURE**

With today’s fiscal realities, FDA cannot rely on government-funded “Manhattan projects” to bridge the funding gap for regulatory science. And with the meteoric rise in scientific knowledge and complexity, the agency cannot rely on federal scientists alone to provide all of the expertise required to innovate in the regulatory science space. Partnerships bring together private-sector expertise, academic science ingenuity, and federal regulatory knowledge, and new structures are needed to promote these multifaceted collaborations.

It would be convenient if such partnerships formed organically, but all too often, bureaucratic red tape gets in the way of sensible scientific collaboration. The MDIC will serve as a collaborative freeway to biomedical discovery and development by forming a foundation that makes it easy for industry, academia, and government to come together to set research priorities; to pool their distinct intellectual capital; and then to work together to advance knowledge that modernizes regulatory science and improves patient access to high-quality medical technology.

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**Table 1. Device use.** Number of procedures in the United States (2009). Source: U.S. Centers of Disease Control (www.cdc.gov/nchs/fastats/insur.htm).

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Number of Procedures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion of coronary artery stent</td>
<td>528,000</td>
</tr>
<tr>
<td>Diagnostic ultrasound</td>
<td>902,000</td>
</tr>
<tr>
<td>CT scan</td>
<td>497,000</td>
</tr>
<tr>
<td>Arteriography and angiography</td>
<td>1.9 million</td>
</tr>
<tr>
<td>Cardiac catheterization</td>
<td>1.1 million</td>
</tr>
<tr>
<td>Total hip replacement</td>
<td>327,000</td>
</tr>
<tr>
<td>Total knee replacement</td>
<td>676,000</td>
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