Role of Public-Private Partnerships (PPP) in the Medical Device Sector
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The development path for medical products under the Food and Drug Administration’s (FDA’s) regulatory purview is costly and time intensive. Both FDA’s Critical Path Initiative (CPI) and the Advancing Regulatory Science (ARS) initiative have attempted to make this pathway efficient by harnessing new technologies and expertise from outside FDA to develop the tools, standards, and approaches required to assess the safety, efficacy, quality, and performance of innovative products. These initiatives also emphasize that bringing regulatory science into the 21st century requires the collaborative efforts of all stakeholders—including academia, industry, and other government agencies. As such, FDA and its various product-development Centers (CDER, CBER, and CDRH) have launched numerous programs in previous years to address the hurdles in the medical product development pathway.

To optimally use limited resources and both internal and external expertise, therefore, non-traditional business models have been developed to tackle complex scientific problems and to help FDA make sound and timely regulatory decisions. Indeed, the high demand for safer, more effective, and less costly regulated products has created an imperative for strategic Public-Private Partnerships (PPPs) with stakeholders, and calls for a scenario whereby all partners have a vested interest in the joint efforts—sharing the risks and rewards of these collaborative efforts.

Public-Private Partnerships (PPPs) represent an economically compelling way for FDA and stakeholders to combine their resources and know-how under aligned missions, for the benefit of patients and consumers.
It is critical that companies understand the long-term benefits of PPP and equally understand the challenges and recommendations made by the industry. The early, pre-competitive stages of medical product development present an ideal time for FDA and other stakeholders to work collaboratively in a PPP, while developing clear expectations for data requirements, standards for product quality and common research tools that would facilitate timely access by patients. It is critical that all stakeholders understand the long-term benefits of PPPs so that all partners have an informed and vested interest in the joint efforts—sharing the risks and rewards of these collaborations.

Examples of PPPs that exist to support initiatives within CDRH include MDEpiNet, the Medical Device Innovation Consortium (MDIC), and the Cardiac-Safety Research Consortium.

MDEpiNet, started in 2010, has as its mission to develop and implement innovative methods and national/international infrastructure for robust studies and surveillance to improve the understanding of medical device safety and effectiveness throughout the product life cycle.

The MDIC, started in 2012, aims to advance regulatory science in the medical device industry. Through its various project initiatives, MDIC will coordinate the development of methods, tools, and resources used in managing the total product life cycle of a medical device, to improve patient access to cutting-edge medical technology.

The Cardiac-Safety Research Consortium, established in 2006, has as its mission to advance regulatory science specifically related to pre-competitive cardiac safety issues through the collaborative means of a PPP among interested stakeholders.

The above are diverse examples of PPPs that focus on the medical device sector and will collectively provide opportunities for collaboration and advancement of key initiatives that will influence the medical device total product lifecycle. Another proposed PPP is to support the implementation, development, and management of a National Medical Device Surveillance System, as proposed recently in a report commissioned by FDA and completed by the Engelberg Center (Brookings Institute).

Numerous business models can be developed to facilitate implementation of different PPPs, depending on the scientific goals, the resources available, the partners involved, and the different resources available to each. Regardless of their scope and objectives, PPPs can achieve synergies in which the whole is greater than the sum of the parts (or partners), and such collaborative entities can make great strides in product development and regulatory review. Because PPPs represent a feasible mechanism for FDA to accomplish its mission by sharing risks and benefits, FDA has been willing and eager to engage with stakeholders, in appropriate, pre-competitive ways, to facilitate bringing safe and effective medical products to patients.
The early, pre-competitive stages of medical product development present an ideal time for FDA and other stakeholders to work collaboratively, developing clear expectations for data requirements, standards for product quality and common research tools that would facilitate timely access by patients.

Long-Term Benefits of Public-Private Partnerships

- Substantial contribution to the advancement of science and evidence-based medical product development and performance throughout the total product life cycle of product development
- Development of innovative approaches to bridge pre- and post-market activities with the end goal of promoting safe and effective medical products
- Innovative ways to integrate existing and future databases to facilitate regulatory and R&D decisions, all of which are important for go/no-go decisions
- Foster and train the next generation of medical device researchers

Challenges and Recommendations

Several challenges have arisen regarding PPP formation and management. Conflict of interest (COI), both real and perceived, the appearance of impropriety, inconsistent policies, and inconsistent scientific and business decisions are just a few challenges that PPPs have faced. Other potential COIs may arise in the solicitation, receipt, and management of financial resources to sustain the PPP. All of these factors undermine the integrity of FDA, partners within a PPP, and the public trust, and once that trust is compromised, it is extremely difficult to regain. It is imperative, therefore, that these pitfalls be avoided by establishing mitigation strategies at the outset of PPP formation, to maintain the credibility of the partners and the integrity of regulatory decisions.

It has been successfully demonstrated that intellectual capital from federal employees, academicians, and private industry staff can be form the basis for scientific innovation and timely product development. This is evident in the dozens of collaborative projects and PPPs launched in previous years that have contributed to the advancement of science and development of tools, know-how, and data to foster medical product development, disease management, and patient care. However, it is recommended that such efforts should never be undertaken with a specific sponsor’s product in mind.
It must be understood that the data and conclusions generated from such joint efforts should benefit science in general and classes of medical products. It is also recommended that generalizable data and scientific findings be shared in the public domain in a transparent manner, and that any regulatory policies, recommendations, and guidance generated from such efforts be applied transparently and consistently in regulatory decision making. In this way, the public will not perceive any competitive advantage to one sponsor over another.

For Further Information or Questions, Please Contact:

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i. The term medical product includes drug and biological products, as well as medical devices associated with the Center for Devices and Radiological Health (CDRH); the Center for Biological Evaluations and Research (CBER), and the Center for Drug Evaluation and Research (CDER)

