FDA announces public-private partnership to develop regulatory science that will speed patient access to new medical device technologies

The U.S. Food and Drug Administration announced today that it is part of the first public-private partnership to promote medical device regulatory science with a focus on speeding the development, assessment, and review of new medical devices.

The new Medical Device Innovation Consortium [1] (MDIC) is an independent, nonprofit corporation, created by LifeScience Alley [2] (LSA), a biomedical science trade association. The MDIC will receive input from industry, government, and other nonprofit organizations. MDIC will prioritize the regulatory science needs of the medical device community and fund projects to help simplify the process of medical device design and pathway to market for these innovations.

Regulatory science – the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products – is critical to the medical device industry and to public health. Advancements in regulatory science not only aim to improve how products are developed and evaluated, but also could reduce the cost and time it takes for a promising device to come to market. For example, a computer model might be developed to test an implant on a virtual patient before a manufacturer spends the time and budget to study that product in a clinical trial.

The MDIC will bolster the country's investment in regulatory science research by pooling people, funding, resources, and ideas to develop new tools, models, and methods that may be utilized to better and more efficiently evaluate new devices. FDA staff may collaborate with the MDIC on MDIC-supported research and other projects.

"By sharing and leveraging resources, MDIC may help industry to be better equipped to bring safe and effective medical devices to market more quickly and at a lower cost," said Jeffrey Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Links:
[1] http://www.deviceconsortium.org/
[2] http://www.lifesciencealley.org/