# FDA Educating to Improve Regulatory Review of AI-Driven Technology

FDA continues to be active in emphasizing the importance of artificial intelligence in health care. Now, FDA has committed to a program of creating a knowledgeable, sustainable, and agile data science workforce ready to review and approve devices based on artificial intelligence.

In April of last year, FDA Commissioner Scott Gottlieb, in discussing the transformation of FDA's approach to digital health, stated that one of the most promising digital health tools is Artificial Intelligence ("AI"). Then, in September of 2018, the commissioner again referenced AI as one of the drivers of unparalleled period of innovation in manufacturing medical devices. And, we saw FDA approve a record number of AI devices in 2018.

On January 28, 2019, Gottlieb announced that Information Exchange and Data Transformation (INFORMED), an incubator for collaborative oncology regulatory science research focused on supporting innovations that enhance FDA's mission of promotion and protection of the public health, is going to be working with FDA's medical product centers. Together, they will develop an FDA curriculum on machine learning and artificial intelligence, in partnership with external academic partners.

INFORMED was founded upon expanding organizational and technical infrastructure for big data analytics and examining modern approaches in evidence generation to support regulatory decisions. One of its missions is to identify opportunities for machine learning and artificial intelligence to improve existing regulatory decision-making. So, it makes sense for FDA to use this already existing incubator (although oncology focused) to facilitate increasing knowledge across all of its centers. While it is unclear what the curriculum will look like and who the "academic partners" are, the announcement by FDA that they are seeking the assistance of outside consultants and committing to training its personnel in anticipation of the growth of AI in health care is an important advancement for all those engaged in the development of AI-based devices.