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SYMPOSIUM

Personalized Medicine in Diabetes: Regulatory Considerations

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Abstract

Personalized medicine has become a topic of great interest because of its potential to improve patient care and optimize therapeutic strategy. The U.S. Food and Drug Administration (FDA) is interested in promoting personalized medicine, whenever appropriate, to protect and promote the public health. The ability to better diagnose, screen, and manage patients with diabetes in order to individualize care should lead to better health outcomes and a large benefit to public health. This article describes FDA regulatory considerations for devices intended for use as personalized medicine tools for the diagnosis and treatment of patients with diabetes.

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Abbreviations: (CDRH) Center for Devices and Radiological Health, (FDA) Food and Drug Administration, (IDE) investigational device exemption, (IVD) *in vitro* diagnostic device, (IVDMIA) *in vitro* diagnostic multivariate index assay, (R&D) research and development

Keywords: diabetes, Food and Drug Administration, *in vitro* diagnostics, personalized medicine, regulation

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