Diabetes and Biomarkers

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Abstract

Biomarkers play an integral part in conducting clinical trials and treating patients. In most instances, they help medical practitioners, researchers, and regulatory officials make well-informed, scientifically sound decisions. However, in clinical studies, there is often uncertainty in how much weight to place on biomarker results versus clinical outcomes. This uncertainty emanates from opposing goals of the drug approval process. On one hand, the process must ensure that all therapeutics tested are safe and that the benefits outweigh the risks. On the other hand, the process should allow therapies to be accessible to patients as quickly as reasonably possible. Judicious use of biomarkers in the drug development process can bring these goals into alignment. More efficient discovery and use of biomarkers in the development of antidiabetes drugs will depend on advancing our understanding of the pathogenesis of diabetes and especially its macrovascular complications.

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Abbreviations: (CAST) Cardiac Arrhythmia Suppression Trial, (FDA) Food and Drug Administration, (GWA) genome-wide association, (HbA1c) hemoglobin A1c, (HDL) high-density lipoprotein, (LDL) low-density lipoprotein, (SNP) single-nucleotide polymorphism

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