Society for Immunotherapy of Cancer

Congressional Report Language

FISCAL YEAR 2021

FDA Report Language

Cancer Immunotherapy Clinical Trials.— The Committee is encouraged by the FDA's ongoing efforts to accelerate review and approval of cancer immunotherapies. This has greatly improved cancer patient outcomes by offering reduced toxicities and enhanced quality of life. As cancer treatment advances, the development of combination therapies relying on immunotherapy as a backbone may further enhance efficacy in patients that typically may not do well. Immunotherapy-based combination treatments, however, introduce many nuances – including the sequencing of involved agents and potential toxicities that can arise – that are difficult to compare across available data and trial designs. Therefore, in anticipation of an influx of new clinical trials involving combination regimens, the Committee urges the FDA to work with and provide guidance to the research community and pharmaceutical industry surrounding standardized clinical trial design considerations for immunotherapy-based combinations in order to help clinicians better select optimal treatment options for their patients, as well as expedite regulatory review of novel regimens.