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Regulatory considerations for *in vitro* diagnostics in oncology

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Advancements and innovation in the development of *in vitro* diagnostic (IVD) devices are important for the success of personalized medicine. At FDA, the development of targeted therapies and the associated diagnostics have been a priority since the first companion diagnostic and corresponding drugs were approved in 1998. Since this time, there has been a dramatic increase in biomarker-targeted drug development programs; in 2013, approximately 45% of new drug approvals were for targeted therapies, and there are currently upwards of 25 approved companion diagnostic devices. When a device is considered for marketing authorization, FDA relies upon valid scientific evidence to determine whether there is reasonable assurance that a device is safe and effective for its intended use. During this presentation, the author will provide an overview of the regulatory framework for IVDs and discuss validation considerations for IVDs. In addition, there will be highlights about challenges and strategies related to the use of diagnostics in biomarker-driven clinical trials and finally the study will summarize recent FDA approvals of diagnostic devices for cancer therapeutics.

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