Soma Ghosh, J Cancer Sci Ther 2017, 9:10 (Suppl)
DOI: 10.4172/1948-5956-C1-113

Soma Ghosh

US Food and Drug Administration, USA

Regulatory considerations for *in vitro* diagnostics in oncology

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 drug 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 my presentation, I will provide an overview of the regulatory framework for IVDs and discuss validation considerations for IVDs. In addition, I will highlight challenges and strategies related to the use of diagnostics in biomarker-driven clinical trials, and I will summarize recent FDA approvals of diagnostic devices for cancer therapeutics.

Biography

Soma Ghosh continued her training in Molecular Biology at the National Institutes of Health (NIH/NICHD), Bethesda, MD, where her work dealt with the mechanisms that regulate cellular DNA replication during animal development; after completing her Doctoral degree from the School of Life Sciences at Jawaharlal Nehru University, New Delhi, India. Her focus then shifted to development of sequencing-based assays to support clinical decision making in cancer therapy and management, an area she pursed as a Molecular Geneticist at the Sidney Kimmel Comprehensive Cancer Center in Johns Hopkins Medical Institute. Currently, she is a Regulatory Scientist at the FDA where she is actively involved in the review and approval of companion diagnostic devices.

Soma.Ghosh@fda.hhs.gov