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 pursued 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.

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