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Quantitative PCR-based cancer biomarker assays in clinical trials

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Biomarkers have many significant applications in oncology, including diagnosis, prognosis, risk assessment, prediction of response to treatment and screening and monitoring progression of the disease. Further, cancer biomarkers play an important role during all phases of drug discovery and development and in guiding early decision in clinical trials. Real-time quantitative polymerase chain reaction (RT-qPCR) technology has become the method of choice for clinical biomarker detection and quantification since it is accurate, sensitive, fast and relatively cheaper than other available gene expression-based technologies. Although a thorough analytical and clinical biomarker assay validation is not required for discovery-phase work, as a drug progresses into preclinical and early-phase clinical studies, it becomes important to have more rigorously qualified biomarkers. A "fit-for purpose" assay development and validation to meet the clinical requirements plays a significant role in cancer biomarker quantification. Development and use of RT-qPCR technology for robust, accurate and reliable method is required for the "fit-for-purpose" biomarker assay qualification. Few important factors influencing assay performance such as sample matrix, sample preparation, experimental precision, reproducibility, sensitivity, specificity, dilution linearity and dynamic range and their impact on the assay outcome will be discussed. Based on these, we will put forth recommendations for consideration and optimization of qPCR-based clinical cancer biomarker assays by demonstrating a few examples. Lastly, a few representative case studies of safety/efficacy and pharmacodynamic cancer biomarkers will be discussed that exemplify enabling of early decision making in Oncology and Immuno-oncology clinical trials.

Biography

Shashwati Basak serves as the Head and Sr. Lead Investigator of Clinical Genomics Group in Exploratory Clinical and Translational Research (ECTR), Biocon Bristol-Myers Squibb Research and Development Center (BBRC), Bangalore. She started the ECTR department in 2010 and played an instrumental role in setting up the Clinical Biomarkers laboratories at BBRC. Her current research interests involve assay development and qualification of Clinical Biomarkers, especially in Oncology and Immuno-oncology and its use in clinical trials, while collaborating with multiple internal teams and global stakeholders. Her other interests are to pursue exploratory and translational research to understand the underlying mechanisms of cancer. In her additional roles, she also provides leadership in Managing the regulatory paperwork and clinical sample logistics to handle global clinical trial sample shipments for BMS to support the clinical biomarker work. She obtained a PhD in Molecular and Cellular Biology from the Indian Institute of Science, Bangalore and studied DNA-protein interactions to decipher novel transcription activation mechanisms in prokaryotic model systems. She carried out Post-doctoral research from The Salk Institute for Biological Sciences, San Diego and Stanford School of Medicine, Palo Alto. Her research in these two places was focused on understanding the intriguing complexities of cancer signaling pathways. She worked as a Research Scientist in the Veterans Affairs Medical Center (VAMC), San Francisco on multiple projects involving translational research in cancer. She has published her research work in numerous top peer-reviewed international journals such as cell, molecular cell etc. She has also served as a Reviewer for many American Association of Cancer Research (AACR) Journals like *Cancer Research and Clinical Cancer Research* and written and obtained international grants.

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