Yiu-Lian Fong, J Cancer Sci Ther 2016, 8:10(Suppl)
http://dx.doi.org/10.4172/1948-5956.C1.093

14th World Cancer & Anti-Cancer Therapy Convention

November 21-23, 2016 Dubai, UAE

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Advancing translation of cancer biomarkers to dx applications: The opportunities, challenges and lessons learned

In the past decade, the fast advancing of molecular technologies has dramatically fueled cancer research and biomarker discoveries. The discovery and development of cancer biomarkers continue to elucidate that cancer is a group of complex diseases which involve diverse and intertwined molecular pathways and impaired regulatory mechanisms. Advances in the understanding of the disease mechanisms at the molecular level and the accompanied development of cancer biomarkers have not only dramatically facilitated the development of diagnostic and prognosis tools but more importantly have also created enormous opportunities for identifying novel drug targets, accelerating novel drug development, and enabling targeted therapies. The successful inclusion of biomarkers in clinical trial designs has created a paradigm shift for the potential requirements of co-development and regulatory approval of the companion diagnostics, especially if the biomarkers are proven to be effective in differentiating responders from the non-responders. Incorporation of predictive biomarkers into clinical trial is deemed crucial not only for successful drug development but also for health economics. However, despite the paramount effort and investment, successful translation of novel biomarkers from research into clinical practice is still very difficult and limited. In addition to the challenges associated with the intrinsic heterogeneity of cancer biology that may hamper the successful applications of cancer biomarkers, the major issues for translating biomarkers from research to diagnostic applications reside in the lack of fundamental knowledge of the practical differences for the development and validation of biomarkers for basic or clinical research versus for the development and validation of diagnostics for the regulated intended use.

Biography

Yiu-Lian Fong has more than 20 years of experience in the health care industry leading and managing R&D teams developing various diagnostic and therapeutic products. For more than 10 years, she has led and directed many R&D projects working on translating biomarkers to in vitro diagnostics for various clinical applications, including early detection, prognosis, risk stratification, therapeutic monitoring and companion diagnostics for various types of cancers. She currently serves as the Global Head for Diagnostic Innovation, Research and Development at Janssen, a J&J company, focusing on developing innovative technologies and solutions to help drive precision medicine.

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