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Pharmacodynamic biomarkers in early phase oncology trials: Opportunities and challenges

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The current process of R&D is not sustainable and there is a big drive for shorter timelines and reduced development costs. In oncology, the number of targeted or immunotherapeutic anti-cancer therapies are on the rise and they are showing significant promise compared to chemotherapy. In early phase oncology clinical development, biomarkers are increasingly being used to identify the right drug for the right patient, at the right dose and schedule in order to clearly demonstrate proof of mechanism and proof of principle. This is fundamentally important as often in early phase oncology trials, demonstrating proof of concept in terms of efficacy is very limited and later stage development is performed at risk. With evolving technologies, numerous methods and assays are being explored to demonstrate biological end points that enable successful go/no-go decision for further development and thereby helping to minimize phase II attrition. Surrogate end points, in addition to tumor markers, add more confidence to overall trial success. Despite this, there are number of limitations and challenges in using biomarkers in early phase oncology trials, including obtaining paired biopsies, successful immune-monitoring, correlation between tumor and surrogate end point and clinical response and making sense of large amounts of data. Despite these challenges, a positive and optimistic outlook prevails in the use of pharmacodynamic and enrichment markers in early phase trials for ultimate patient benefit.

Biography

Sidath Katugampola completed his PhD in Cambridge. He worked across multiple departments, spanning over 11 years at Pfizer Research UK. During his last 6 years at Pfizer Sid, he led projects in Biomarkers and Translational Medicine across multiple therapeutic areas and targets. From the past 3 years of his career, he has been working at the Centre for Drug Development at Cancer Research UK where he is responsible for delivering pharmacodynamic biomarkers, across multiple modalities and cancer types, in early phase oncology clinical trials, the majority of which are first in class agents.

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