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## Biomarkers in early phase oncology clinical development

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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 anti-cancer therapies is on the rise and they are showing significant promise both in terms of efficacy and improved safety profile compared to conventional 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 & 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. Circulating markers, in particular ctDNA has shown significant promise as a liquid biopsy. Following dose escalation, a growing number of trials now incorporate expansion arms with patient enrichment strategies. There are number of limitations and challenges in using biomarkers in early phase oncology trials, including making sense of large data sets. 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

Sid 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 he led projects in biomarkers and translational medicine across multiple therapeutic areas and targets. 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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