Strategy for determining clinical biomarker panel

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Biomarkers are essential for improving the outcomes of clinical trials and accelerating drug development. Mass spectrometry (MS)-based proteomics applied early to clinical samples has the potential to identify and narrow down predictive and pharmacodynamics biomarkers. These markers can then be used in clinical trials for patient stratification and to increase sensitivity of primary endpoints for a better measurement of therapeutic response. Unbiased proteomic profiling is powerful during the exploratory biomarker stage for monitoring hundreds or thousands of proteins, but throughput is low and relative quantitation is variable for low abundant analytes. Here, we describe an integrated, hypothesis-driven strategy that combines unbiased proteomics and literature mining to generate a highly quantitative and reproducible targeted proteomics assay for testing in large, representative patient cohorts for candidate biomarker screening. Combined with appropriate statistical and bioinformatics processes, this strategy will facilitate selection of a robust biomarker panel which may be validated as a companion diagnostic or as a clinical tool.

Biography

Oliva Petra has 10 years of biotech experience and close to 20 years scientific expertise in an advanced interdisciplinary research in analytical chemistry, biotechnology and biochemistry with deep understanding of biomarker discovery, qualification and validation. She is currently Pr. Scientist at Translational Science group within Sanofi, US. She is managing analytical/bioanalytical support from pre-clinical stage, through PhI & PhII all the way to the commercial phase. Petra and her team established several innovation platforms (as targeted proteomics & MS imaging) winning multiple global Sanofi awards. She also has 8 years collaboration with CDC on LSD newborn screening.

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