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Development and implementation of metabolomics platform: Considerations for successful discovery and validation of biomarkers

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As translational science approach to drug discovery and development is being broadly implemented in pharmaceutical industry we are increasingly relying on metabolic biomarkers in all phases of the process, including target credentialing, proof of concept, establishment of biomarkers based screens, in vivo studies, clinical studies and establishment of biomarker based diagnostics. In cases when biomarkers are not known, metabolomics platform becomes an essential tool for holistic and unbiased interrogation of thousands of metabolites and identification of metabolic biomarkers. Identification of biomarkers is based on global profiling using chromatographic separation coupled with high resolution accurate mass spectrometric detection (HRAM). Processing of the data is carried out using sophisticated peak picking software, statistical packages and working with data bases. Since there is no single “of the shelf” product enabling to carry out all the data processing steps for metabolomics, this is especially challenging. Exact molecular mass information available in public data bases typically allows only for tentative identification of the biomarkers and often results in multiple options which have to be evaluated in additional experiments. This is both expensive and time consuming. In this presentation we will describe analytical platform for metabolomics established at AR&D / LGCR in Sanofi as a result of multiple applications and cross-departmental collaborations. We will discuss considerations for development of methodology for sample preparation and analysis using LC-HRAM, as well as approach for construction of an in-house metabolomics data base and demonstrate our data processing approach based on trends and correlation analysis allowing for identification of phenotype-linked biomarkers with much reduced effort.

Biography

Alla Kloss has a Masters Degree in Chemical Engineering from The Institute of Technology (St. Petersburg Russia), and has also completed her PhD in Physical/Analytical Chemistry from University of California, Davis and Post Doctoral studies at the University of Illinois at Urbana-Champaign. She is a Scientific Director at Analytical Research and Development Department in LGCR, Sanofi where she leads a biomarker discovery group.

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