

Challenges and Strategies for Generating and Interpreting Clinical Biomarker Data.

A Case Study

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In current drug development, biomarkers are increasingly used to understand the mechanism of diseases and to evaluate the effectiveness of drug candidates. More and more frequently, biomarker data influences drug development decisions. Therefore, it is essential to ensure high-quality bioanalytical methods are used, and meaningful data are generated. This can be complicated for biomarkers due to challenges such as the endogenous analytes present in control matrix, inter- and intra-subject variability, the instable nature of some biomarkers, and so on.

This presentation will demonstrate the application of an LC-MS/MS assay for measurement of fatty acid amides. Specifically, arachidonyl ethanolamide (AEA), oleoyl ethanolamide (OEA), and palmitoyl ethanolamide (PEA) are quantified as biomarkers for the development of fatty acid amide hydrolase (FAAH) inhibitors. Examples of the challenges involved in the evaluations of biomarkers, and the strategies that are proposed to overcome the problems, will be presented.