

Clinical Chemistry Workshop, ASMS

“Mind the (Translation) Gap”

Chair: Brian Rappold, LabCorp

Panel:

Mike Morris, Waters Corporation

Tim Collier, Quest Diagnostics

Gustavo Salem, Eureka Life Science

Moving a technology or a biomarker to actual clinical deployment is a challenging venture beyond the nature of the analytical process. In the 2023 Clinical Chemistry workshop, 3 experts in translation of work from discovery to utilization on human patients offered their wisdom and wit to the attendees. Utilizing 2 fictitious biomarkers and 1 imaginary device intended to be used in diagnostic medicine the panel and the attendees discussed the non-chemistry related aspects of translating methods or materials to the clinic. The panel represented 3 facets of the industry: commercial reference laboratories, a vendor of in-vitro diagnostic devices and venture capital.

The attendees provided some interesting discussion guided by the panelists. There was a misconception regarding reimbursement for MS based diagnostic testing with some attendees proposing prices in the thousands of dollars. The panel accurately identified the compensation in the United States, as dictated by the Congressional Medical Services (CMS), to be approximately twenty-five dollars. Further, the complexities of “Intended Use” of a test or device were explored, especially regarding the untargeted approaches. In the fantasy example of a biomarker to identify “teenage attitude”, the panel and attendees discussed the ethics of performing certain tests, which spanned the gamut of “medically-necessary” considerations.

While biomarkers are certainly a challenge, the workshop also discussed mechanisms to bring new technology to a diagnostic market. While the example of “touchless” micro-sampling device was rightly identified as outlandish by the attendees, the oversight role of the FDA, quality manufacturing and other nuances of medical device manufacturing were examined between the panel and the attendees. While often humorous, the dialog amongst the attendees illustrated many of the important features that should be considered in moving from discovery to actual clinical use and provided items for consideration as more and more mass spectrometry users venture into clinical applications.

The program and co-coordinator for 2024 has not yet been determined.