



## Biomarkers for Drug Development: How are we dealing with the challenges?

Sue Jane Wang, of the FDA led the session on “Biomarkers for Drug Development” at DIA 2013. The expert panel present had many collective years of experience in the field of biomarkers and included Tom Jacobs (Janssen R&D), Christine Blazynski, (Citeline), and Will Treppichio (Takeda Oncology Co.). Each panelist highlighted their perspective on how biomarkers are evolving to be a critical piece of the drug development puzzle that the industry is racing against time and dollars to solve. Tom Jacobs gave a statistician’s perspective on biomarkers in Alzheimer’s particularly highlighting major pain points faced in neuroscience drug discovery: translation of cognitive models from animals to humans, need for validated biomarkers for diagnosis and progression, and finally need for better basic science research to aid clinical trial design.

Christine Blazynski of Citeline attempted to debunk the myth that clinical trials are longer and more costly today than at any other time in drug discovery. With a comprehensive view of multiple parameters like trial duration and time taken to meet primary end points, she presented analyses of clinical trials conducted in breast cancer and non small cell lung cancer (NSCLC). Her findings suggest that overall trial durations have actually decreased since 2008-9 in breast cancer, NSCLC and targeted therapies. This data suggest that the increase in geographic breadth and new sites being utilized for global clinical trials might be the real cause for increasing costs of clinical trials developers are facing today.

Bill Trepicchio showcased the use of proteasomal inhibitor, bortezomib in follicular lymphoma and multiple myeloma. He discussed retrospective studies on grouping patients with genetic differences (short nucleotide polymorphisms) in particular biomarker genes showed meaningful medical benefit between bortezomib treated vs untreated patients, compared to total intent to treat population. He also raised an excellent point on timing of protocol amendment to include data collected during the clinical trial, which would allow this data to then be used in regulatory filing. Overall, the panel did a fantastic job of highlighting biomarker utility and development, current successes as well as future challenges.