

## DIA 2013 49<sup>th</sup> Annual Meeting "Advancing Therapeutic Innovation and Regulatory Science" June 23 – 27, 2013 Boston Convention and Exhibition Center Boston, MA

## Session 332 – Pharmacometrics: Implications and Impact in Preclinical to Early Phase Development

Drug development is experiencing a fundamental change in the way clinical trial data are analyzed to achieve therapeutic efficacy and safety. To assess the role of pharmacometrics, DIA 2013 presented *Pharmacometrics: Implications and Impact in Preclinical to Early Phase Development* (Session 332). "Increasingly, sponsors and regulators are being driven by pharmacometrics", enthused Session Chair Royce Morrison, MD, MS (Quorum Review, Inc).

In *Pharmacometrics Drives Drug Approval and Labeling Decisions*, Jogarao Gobburu, PhD, MBA (University of Maryland) drew on his 14-year experience at the FDA, to provide a regulatory perspective on the importance of pharmacometrics. Using Tripleptal and Everolimus, he described case studies in which the FDA worked with drug developers to use pharmacometrics to rescue drugs that would have been discarded but instead, are now marketed for several indications. "It is a business-wise decision to invest in pharmacometrics. FDA has done it, and I hope businesses will follow suit", he concluded.

Arnab Mukherjee, PhD, (Pfizer) offered a drug developer's perspective in *Pharmacometrics Impacts Drug Development Decisions: Big Pharma Experience*. He explained that modeling-based drug development has increased Pfizer's phase III success rate from 50% in 2005 to 80% in 2009, but highlighted several challenges that must be overcome by top management support and increased access to ongoing clinical trial data.

Session Chair Royce Morrison concluded with *Opportunities to Take Advantage of Pharmacometrics*, where he highlighted pharmacometric training resources and new funding opportunities to move the field forward because "pharmacometrics is a paradigm shift in the way we approach making decisions".

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