Modeling Without Finish Line - Personalized Medicine by Quantitative Pharmacology In the Post-Approval Space

Co-Chairs
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Description
Drug development has focused on treating the average patient, ignoring differences between individuals. Quantitative Pharmacology has provided significant advances in changing this paradigm by analyzing variability in drug exposure/response and identifying sub-groups that need dose adjustments. This is typically performed only during the development phase of a drug and not always translated into clinical practice. With the increasing focus on precision medicine, which tailors therapy by taking into account individual variability in genes, environment, and lifestyle for each patient, an important opportunity is available to the field of Quantitative Pharmacology to optimize drug therapy in real clinical practice. This symposium will describe opportunities for quantitative pharmacology in precision medicine, focusing on the post-approval space where modeling and simulation can be developed using big data collected in clinical practice to inform individualized prescribing of drugs.

Learning Objectives
- Describe an overview of precision medicine and how this concept fits into the larger health care continuum
- Describe how clinical pharmacology and pharmacometrics can impact precision medicine in the next decade
- Review a case studies of quantitative approaches used to assess individualized treatment of drugs.
- Describe how data collected in clinical practice can be used for individualized prescription and utilization of drugs
Session Speakers and Presentations

**Joga Gobburu** - Precision Medicine: Opportunity for Clinical Pharmacology/Pharmacometrics.

**Matts Kagedal** - Herceptin in Gastric Cancer: Exposure response analysis for overall survival based on two dose levels.

This presentation will focus on how modeling and simulation helped the understanding of E-R confounding and dose optimization for Herceptin in a new indication with additional trial and analysis (PMC/PMR).

**Sandy Aronson** - Strategic Use of Information Technology Interventions to Affect Clinical Care Evolution

Ultimately the adoption of every advance in clinical medicine, whether it be a drug, incorporation of a new type of data in the diagnostic process or new process, requires people involved in the clinical workflow to make changes. They have to change the way they make decisions or change the way they interact with patients or both. The need for these changes are a major impediment to medical progress. There is not any slack in the healthcare deliver system today so changes that require increases in clinician workload often are not feasible to implement. One way to address this problem is to build specific information technology support to make it possible to transition to the new process flow. This talk will discuss the process of creating and implementing these types of information technology interventions.

**Hilary Luderer** - reSET Digital Therapeutic for SUD Demonstrates Dose-Dependent Improvement in Outcomes

Poster abstract speaker - Poster T-086  Tuesday 1-2 PM