

## **M-CERSI Science Exchange Award**

**Conference Title:** Regulatory Issues in Next-Generation Medicine and Pharmacogenomics

**Principal Investigator:** Alan Shuldiner, MD and Michael Pacanowski, PharmD

**Workshop Date:** September 3, 2013

**Outcomes/Summary:**

**The primary goal of this conference was to facilitate a discussion between FDA scientists, academic scientists and other stakeholders regarding the regulatory issues in nextgen sequencing applications to pharmacogenomics and personalized medicine. Topics that were discussed:**

- **Non-clinical pharmacogenomic models and their role in supporting activity/pharmacogenomic interactions (e.g., across different tumor mutations)**
- **Approaches to subsetting patients in clinical trials based on rare features using high-throughput technologies (e.g., what is the development pathway for handling large structural variations that define a disease)**
- **Education and dissemination of pharmacogenomics information to the community and clinicians (e.g., decision support tools)**

### **Expected achievements and outcomes**

- The discussion regarding regulatory issues in nextgen medicine will serve to contribute to the advancements in developing new tools, standards and approaches to assess the safety, efficacy, quality and performance of FDA-regulated products
- Increase education and awareness of the regulatory issues involved in nextgen sequencing applications to pharmacogenomics and personalized medicine.
- Create a new line of communication between FDA scientists, academic scientists and other stakeholders regarding regulatory issues in nextgen medicine.