

***In silico* approach to biomarker discovery and precision medicine applications pertaining to medical devices**

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Translational research involving pharmacoepidemiologic and pharmacogenetic applications is critically important for enabling access to safe and effective medical products. The ongoing efforts for predictive evaluation of real-world performance of medical devices at the Division of Epidemiology at the Center for Devices and Radiological Health include development of an *in silico* framework that is based on re-utilization of pre-existing epidemiologic and genetic data and that is aimed to identify candidate biomarkers indicative of device performance. The current presentation will share experience from a number of projects on the discovery of device-related biomarkers guided by epidemiologic evidence. As an example, a retrospective analysis of discharges from the Nationwide Inpatient Sample from Agency for Healthcare Research and Quality (NIS/AHRQ) will be presented as a preliminary step for the discovery of candidate SNPs using Personalized Medicine Research Project data on hip arthroplasty outcomes from Marshfield Clinic Research Institute (PMRP/MCRI). The presentation will also include use of causal analytics approaches (ingenuity pathway analysis) for exploring functional plausibility of the identified candidate SNPs indicative of periprosthetic osteolysis in the sex/race-stratified subpopulations with hip arthroplasty. As a result, the presentation will render new *in silico* approaches that reutilize pre-existing (genetic and epidemiologic) data and that thus can augment the evidentiary needs for development of cost/time-efficient precision medicine applications.

Biography

Yelizaveta (Lisa) Torosyan is an interdisciplinary MD/PhD Scientist with clinical background and extensive biomedical expertise including translational research with potential health care applications. She is currently working at the Center for Devices and Radiological Health, Food and Drug Administration (CDRH/FDA) and her research involves *in silico* synthesis of epidemiologic and genetic evidence for discovery of biomarkers indicative of device performance.

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