2019 America's Got Regulatory Science Talent Competitions
Presentation Abstracts & Student Biographies

University of Maryland	
1st Place Team	**"Never Generic"** **Regulatory Standards for the Safety and Efficacy of Wearable Medical Technologies**
Team Member Members	**Khang Nong, Thomas Adriaens, Kira Aldrich, Uyen Nguyen, and Mary Zhang**
Presentation Abstract	There are an abundance of medical devices and technologies entering the market, from wearable atrial fibrillation monitors to EEG headbands. Currently, there are guidelines and legislation regarding the safety and efficacy of these devices, but they allow devices that are not fully reliable onto the market. With the increasing release of medical technologies, a strengthening of these recommendations and guidelines are required in order to protect patients and give them assurance of what they are using. The aim of this project was to identify any potential gaps and disconnects, and provide recommendations concerning the safety and efficacy of these devices in order to prepare for the future.
Team Member Bios	
Khang Nong	Khang Nong is a third-year pharmacy student at the University of Maryland School of Pharmacy (UMSOP). He is currently conducting research regarding pharmacokinetic changes due to extracorporeal membrane oxygenation as well as research regarding the clinical use of bulk drug substances to assist the production of the FDA 503B bulk substances list. He recently completed an internship with the United States Pharmacopeia where he helped establish a framework for the information distribution of the recently revised general chapters while also conducting health economics research. His career interests lie in regulatory affairs and clinical development.
Thomas Adriaens	Thomas Adriaens is a third-year student at the University of Maryland School of Pharmacy (UMSOP) pursuing his PharmD/MS dual degree in regulatory sciences. He is currently the President of the UMSOP chapter of the Academy of Managed Care Pharmacy (AMCP) where he helped the chapter achieve national recognition when they were awarded AMCP Chapter of the Year. Thomas recently conducted health economics and outcomes research at UMSOP. He has also completed two internships: one in data management and another in pharmacovigilance. His career interests lie in oncology clinical development in which he wishes to pursue a fellowship post-graduation.

Kira Aldrich	Kira Aldrich is a third-year pharmacy student at the University of Maryland School of Pharmacy (UMSOP). Currently the President of the UMSOP chapter of the College of Psychiatric and Neurologic Pharmacists while also conducting patient-centered outcomes research regarding antipsychotics in the pediatric population, Kira is interested in the psychiatric aspects of pharmacy. She has recently completed an internship in medical affairs and wishes to translate this experience towards her professional goals of pursuing a career in medical affairs in the pharmaceutical industry.
Uyen Nguyen	Uyen Nguyen is a third-year pharmacy student at the University of Maryland School of Pharmacy (UMSOP). Uyen is the Vice President of the UMSOP chapter of the Industry Pharmacists Organization where she helped the organization achieve official recognized status and funding from the school. She is currently conducting meta-analysis research to discover contributing factors of dropout rates for substance use disorder patients in cognitive behavioral therapy. With her background in Finance from the Robert H. Smith School of Business combined with her entrepreneurial drive, Uyen wishes to pursue a career in medical affairs.
Mary Zhang	Mary Zhang is a third-year pharmacy student at the University of Maryland School of Pharmacy (UMSOP). Mary has conducted research analyzing discrepancies in studies conducted by health plans, health systems, and drug/device companies. She has also recently completed a pharmacovigilance internship where she reviewed and finalized documents, as well as inspected technology functionality for clinical trial sites for a novel investigational drug to treat AML that was designated Breakthrough Therapy status. Her career interests lie in medical affairs and market access.

University of Maryland	
2nd Place Team	**"The Crown JUULs of ENDS"** **Standardization of a puff from electronic nicotine delivery system**
Team Members	Ana Coutinho, Angela Lee, Bryan Eng, Dongyue Yu, Sharmila Das, and Yuwei Lu
Presentation Abstract	Electronic nicotine delivery systems (ENDS), such as e-cigarettes, are a rapidly emerging technology originally intended to aid with smoking cessation. Currently there is no method for an individual to determine whether they are taking in less nicotine by vaping compared to traditional cigarette smoking. Although many studies and experiments have been done on ENDS products pertaining to their potential toxicity and/or harmful or potentially harmful constituents (HPHCs), it is difficult to compare any of these studies due to the lack of standardization of a "puff." We propose a standardized puff definition outlining the puff duration, inter-puff interval, and air flow rate for first generation e-cigarettes based on numerous puffing topography studies in the literature. Due to rapidly evolving e-cigarette technology, defining a puff for first generation products will set a precedent for other e-cigarette generations. The standard puff can be implemented through an FDA Guidance for Industry and will ultimately allow for more valid comparisons between various studies and products.

Team Member Bios	
Ana Coutinho	Ana Coutinho is a first-year PhD student in the Pharmaceutical Sciences department at the University of Maryland School of Pharmacy. She earned her PharmD degree from the same school and a B.S. in toxicology from the Pennsylvania State University. Her research interests are in clinical trial design, polymer-API interactions in amorphous solid dispersions, and formulation in vitro/in vivo correlation performance. She joined the lab of Dr. James Polli and will be conducting a clinical trial in May of this year.
Angela Lee	Angela Lee is a second-year PhD student in the Pharmaceutical Sciences PhD program at the University of Maryland School of Pharmacy. She received her B.S. in Pharmaceutical Sciences from the University of Sciences in Philadelphia and gained some experience in a small generic pharmaceutical company developing oral solid dosage products before pursuing her PhD. She is currently working under the guidance of Dr. Richard Dalby, focusing on researching various aspects of electronic cigarettes.
Bryan Eng	Bryan Eng is currently a first-year graduate student in the Pharmaceutical Sciences PhD program at the University of Maryland, Baltimore School of Pharmacy. He graduated from Campbell University with this Bachelor of Science in Pharmaceutical Sciences, and he has two years of experience in the pharmaceutical industry developing novel dual & triple combination respiratory products and in a high-throughput respiratory generics company. He has completed a rotation with Dr. Richard Dalby studying the harmful effects of electronic nicotine delivery systems and is currently rotating with Dr. Maureen Kane.
Dongyue Yu	Dongyue Yu is a second-year PhD student in the Pharmaceutical Sciences program at the University of Maryland School of Pharmacy. She got her Bachelor of Science in Pharmacy from China Pharmaceutical University, Nanjing, China, and Master of Science degree in Pharmaceutical Sciences from Wayne State University. She is currently working on her thesis project on the compaction behavior of different materials under Dr. Stephen W. Hoag's guidance.
Sharmila Das	Sharmila Das is a fourth-year PhD candidate at the University of Maryland School of Pharmacy, Pharmaceutical Sciences department. She graduated with a PharmD program from the same school. Under the mentorship of Dr. Polli, her research focuses on the quality of generic drugs and is conducting three clinical studies. Two studies concern whether patients who have a negative view of generic drugs show differences in how their body handles brand and generic anti-epileptic drugs. A third study concerns intravenous sodium ferric gluconate and whether brand and generic versions show similar responses. She is interested in pursuing a career in clinical drug development and neuropsychiatric pharmacy.
Yuwei Lu	Yuwei Lu is a third-year Pharmaceutical Sciences Ph.D. candidate at the University of Maryland School of Pharmacy. She got her B.S degree in Pharmacy with a minor in Pharmacy Administration from Nanjing University of Chinese Medicine and M.S in Nutritional Sciences from University of Minnesota-Twin Cities. She has extensive pharmaceutical research experience in both academia and industry with focus on drug metabolism and formulation development of biologics products including live biotherapeutics and monoclonal antibody. She is doing her thesis research under Dr. Stephen Hoag.

University of Rochester	
1st Place Team	**"My RWD"** **A process to provide individuals increased autonomy over their mobile health data.**
Team Member	**Sarah Hackley**
Presentation Abstract	Participation in a technological society is becoming increasingly important in the era of Big Data and provides opportunities to harness diverse data for personalized medicine; however, individuals using medical devices with data-sharing capabilities lack explicit autonomy over their mobile health data. With the advent of advanced clustering techniques, machine learning, and other forms of artificial intelligence the increasing risk of re-identification from previously anonymized datasets threatens patient privacy, confidentiality agreements, and public trust. Additionally, with proposed programs seeking to utilize real-time patient data from wearables and other mobile devices such as the FDA's Real World Evidence program, it is imperative to have a process for responsible and reliable data collection to both advance regulatory science and address broader societal concerns. My RWD (Real World Data) addresses these issues by providing an efficient and validated process for consented participants to access and share mobile health data with 3rd parties for research purposes, while also increasing autonomy by allowing individuals a mechanism to change their level of participation or opt-out entirely.
Team Member Bio	
Sarah Hackley	Sarah Hackley will graduate from the University of Rochester this May with a B.A. in Bioethics, minors in Legal Studies and Philosophy, a cluster in Technology, Food, and Society, and a citation in Community-Engaged Scholarship. Sarah has a profound interest in the ethics of advancing technologies with applications to digital health and individualized medicine. She will complete her honors research thesis "Artificial Intelligence: Patient Privacy and Public Health" this April and plans to attend law school in the next few years to pursue her passions through the field of health law and policy.