2018 Regulatory Science Talent Competitions
Presentation Abstracts & Student Biographies

University of Maryland	
1st Place Team	**"Original Vector"** **GeneTrack: Capture the Manufacturing Process, Perform Live Tracking, and Identify Individual Adverse Events of CAR-T Therapies**
Team Member Members	Nam Nguyen and Laetitia A. N'Dri (FDA mentor: Million A. Tegenge, CBER Office of Biostatistics & Epidemiology)
Presentation Abstract	CAR T-cell therapy uses an inactive virus to genetically engineer T-cells separated from a patient's blood to produce specific antigen receptors on their surface called chimeric antigen receptors (CARs). Once infused into the patient, the modified T-cells can recognize and kill cancer cells that harbor a specific antigen on their surfaces. The US FDA has recently approved two CAR T-cell therapies, and there are several clinical trials registered in clincaltrial.gov. The manufacturing process for CAR T-cell therapy is highly individualized and involves a number of complex and extensive steps. There are currently very few tools available to capture the manufacturing, distribution, communication among stakeholders, and post-market adverse effect tracking for this therapy. Therefore, we developed GeneTrack, an online database that incorporates already existing FDA.gov framework to employ a new universal tracking system. The system aims to build an extensive database of gene therapy through two main steps: (1) Generation of a unique GeneTracking number, (2) Capturing the full detailed manufacturing process of each CAR-T therapy. The availability of GeneTrack not only streamline manufacturing for CAR T-cell therapy, but also increase transparency and improve collaboration among all stakeholders. Furthermore, it can be integrated into MedWatch to offer individualized adverse event report.
Team Member Bios	
Nam Nguyen	Nam Nguyen is a third-year PharmD/MS (Regulatory Science) student at the University of Maryland School of Pharmacy (UMSOP). During his time at UMSOP, he co-founded the local student chapter of Industry Pharmacists Organization (IPhO). He also completed two summer internships, one focused in clinical development (Shire) and the second focused in translational oncology (Novartis). He is an incoming ORISE fellow for the FDA within Division of Clinical Pharmacology I this summer. Nam is interested in the development of new oncology and cardiology drugs, and he hopes to pursue a career in clinical pharmacology/research/ regulatory science within the industry or federal agency.
Laetitia A. N'Dri	Laetitia N'Dri is a third-year PharmD student at the University of Maryland School of Pharmacy, with a background in chemistry and public health. Her interests lie in health economics & outcomes research (HEOR), with a focus on patient-reported outcomes. Currently, she conducts multidisciplinary research at the Pharmaceutical Health Services Research (PHSR) Department. Her projects include assessing the needs for psychological well-being in Baltimore City adolescents, understanding patient treatment preferences to achieve hypertension goal, and measuring caregivers' choices for the care management of their child. After graduation, Laetitia hopes to obtain a fellowship in HEOR and pursue a career in industry.

University of Maryland	
2nd Place Team	**"AlesiaRx"** **Leveraging artificial intelligence & diverse data to improve medication adherence among patients**
Team Members	Anna Dizik, Jordan Fraker, and Michelle Nguyen (FDA mentor: Christopher St. Clair, CDER Office of the Center Director, Professional Affairs and Stakeholder Engagement)
Presentation Abstract	Medication non-adherence is a prevalent issue that has statistically shown to negatively impact health outcomes. AlesiaRx is a mobile application that harnesses artificial intelligence, diverse data, and accelerometer technology in order to provide a seamless way to improve medication adherence. AlesiaRx will not only equip individual patients with the necessary tools to take their healthcare into their own hands, but also has the potential to enhance the validity of clinical trials by enabling monitoring of adherence during the most critical stages of drug development.
Team Member Bios	
Anna Dizik	Anna Dizik received her Bachelor's in Marketing at the University of Maryland, College Park and is is currently a first-year pharmacy student at the University of Maryland, Baltimore (UMB). She has previously worked in various human subject/ neuroscience research labs, is currently involved in health outcomes research at the Pharmaceutical Health Services Research department at UMB, and generally enjoys working in translational research. She is primarily interested in a career within the pharmaceutical industry, especially in clinical drug development and medical affairs, and is passionate about impacting healthcare on a global scale.
Jordan Fraker	Jordan Fraker studied Neuroscience at Temple University before coming to the University of Maryland to pursue a Doctor of Pharmacy degree. She is interested in optimizing the patient experience through the development of technology that provides patients with both services and solutions. Jordan is currently working on a product to help acquaint patients with their prescription coverage.
Michelle Nguyen	Michelle Nguyen is currently a first-year student pharmacist at the University of Maryland School of Pharmacy with a bachelor's degree in Neurobiology and Physiology from the University of Maryland, College Park. She has a growing interest in regulatory science, but is exploring her interests with ambulatory care at the University of Maryland Medical Center and HIV research at the Walter Reed Army Institute of Research.

University of Rochester	
1st Place Team	**"Dr. Data"** **An Integrated Drug Repurposing Database for Identifying New Indications of FDA Approved Drugs**
Team Member	Xiaowen (Cindy) Wang, M.S.
Presentation Abstract	Drug repurposing, the process of identifying new indications for previously approved drugs, is of growing interest to academia and industry due to the promise of reduced cost and the potential for rapid clinical transition. However, the access to large, complex drug repurposing data sets has not been readily available. This proposal aims to develop a collaborative drug repurposing database to promote new research directions, novel clinical trial designs and biomarker identification. The drug-repurposing database (Dr. Data) would house molecular and clinical data mined from public sources, including all FDA approved drugs under investigation for new uses. A self-report portal will enable investigators from academia and industry to submit ongoing drug repurposing studies. Dr. Data is also embedded with analytical tools which would allow chemical structure processing and signaling pathway analysis. Drugs will be classified based on suggested new uses, fostering identification of common chemical characteristics and protein targets. Predictive analytics will suggest promising repurposing candidates for a given use based on structural similarities and/or common signaling pathways.
Team Member Bio	
Xiaowen (Cindy) Wang	Cindy graduated from University at Buffalo with a B.S. degree in Biomedical Sciences. She was accepted into the Pharmacology and Physiology Graduate Program at the University of Rochester and joined the lab of Dr. Mark Noble in 2015. Cindy earned her M.S. Degree in Pharmacology in 2016 and continued her study to develop novel therapeutic approaches for chemotherapeutics-resistant breast cancer. Cindy remains engaged with the graduate student community and has been awarded multiple travel awards for her outstanding scientific presentations. In 2017, Cindy joined University of Rochester Technology Transfer Office, where she focuses on the commercialization of university's research discoveries.