2017 Regulatory Science Talent Competitions
Presentation Abstracts & Student Biographies

School	**University of Maryland CERSI**
1st Place Team	**"Veni Vidi Vici"** **A high visibility universal labelling system to communicate risks of hazardous drugs**
Team Member	Caitlyn Singam
Presentation Abstract	Federal law defines hazardous chemicals as any chemical that poses a physical or health hazard. A burgeoning segment of the modern arsenal of medications pose a similar risk. Cytotoxic and genotoxic medications are commonly cited examples of what this author classifies as hazardous drugs. However, due to the ambiguity or outright absence of textual warning labels on these medications, individuals who suffer incidental exposure in preparation, handling, administration and disposal of the drug may be compromising their health and safety. The risk posed by hazardous drugs is not limited to those within the healthcare community either, due to the large number of individuals who handle hazardous drugs during the process of manufacturing, transport, administration, and disposal. The author proposes a simple, clear label by which all individuals who come in contact with hazardous drugs – regardless of background – can readily distinguish between hazardous and non-hazardous drugs. The implementation of the proposed labelling system, with a coherent definition of hazardous drugs, has the potential to increase awareness of handling risks for hazardous drugs, thereby improving health, safety, and the environment.
Team Member Bio	
Caitlyn Singam	Caitlyn is a freshman in the Integrated Life Sciences (ILS) Honors Program at the University of Maryland, College Park (UMD), where she was awarded a full Banneker/Key scholarship. Having won her first college scholarship at age eleven, she completed her high school graduation requirements early and began taking college courses at UMD in her junior year of high school. She spends many of her weekends volunteering at a cardiac clinic for disadvantaged patients, and has accrued more than a thousand documented hours serving the needy. Caitlyn aspires to pursue a career in medicine.

School	**University of Maryland CERSI**
2nd Place Team	**"Biomarker Boys"** **Platform to improve transparency for biomarker integration in Accelerated Approval**
Team Members	Fahim Faruque, Sebastian Bilitza, Teddy Dunning, Edwin Oak, Alexander Britcher, and Ankit Gandhi
Presentation Abstract	The aim of our project was to assess and examine primary data from Accelerated Approval reviews and the opinions of key stakeholders to create a form that facilitates transparent and structured integration of biomarkers into rare disease state drug development. Accelerated Approval is of critical importance when it comes to the development of therapeutics for rare disorders. These disease states are challenging to study using routine clinical trials, and the cost of running these trials for approval may further deter the development of therapeutics for these small patient populations. These factors have led to a lack of available therapeutics for many rare diseases. Although relevant documentation supporting drug approvals are publicly available, biomarker---related information may not be easily identifiable in these documents. We hope this method of providing notice will serve to incentivize pharmaceutical companies to pursue this pathway by providing them with a transparent structure, and help accelerate dialogue between the sponsor and the FDA for what is needed for biomarker integration as surrogate endpoints. Additionally, this form will make the information as to why a biomarker was regarded as an appropriate surrogate endpoint transparent to both the public and clinicians.
Team Member Bios	
Fahim Faruque	Fahim Faruque is a third-year pharmacy student at the University of Maryland School of Pharmacy (UM SOP). He is interested in precision medicine, population health, and access to healthcare. During his time at UM SOP, he co-founded the Entrepreneurship & Innovation Network and served as the Vice President of the Academy of Managed Care Pharmacy student chapter. He is currently involved in health economics and outcomes research with faculty in the Pharmaceutical Health Services Research department at UM SOP.
Sebastian Bilitza	Sebastian Bilitza is a second-year pharmacy student at the University of Maryland School of Pharmacy (UM SOP). He is interested in regulatory science, clinical drug development, and psychiatric pharmacy. Currently he is serving as the President of the College of Psychiatric and Neurologic Pharmacists student chapter at UM SOP. Beyond pursuing his PharmD, he is gaining real world experience by working part time as an associate at a clinical and regulatory affairs consulting firm.
Teddy Dunning	Teddy Dunning is a second-year pharmacy student at the University of Maryland School of Pharmacy (UM SOP). His interests lie in medical affairs, clinical development and pharmacokinetics. In pharmacy school, he served as a co-founder and the Director of Operations for the Internship Preparatory and Network Development Series in the Academy of Managed Care Pharmacy student chapter. He is currently involved in pharmacokinetic research at the UM SOP.

Edwin Oak	Edwin Oak is a first-year pharmacy student at the University of Maryland School of Pharmacy (UM SOP). His interests are in regulatory science and entrepreneurship, but he is keeping an open mind in exploring potential career options. He has taken an active role in pursuing leadership roles at UM SOP, collaborating with students in organizing events for the Entrepreneurship & Innovation Network and the Academy of Managed Care student chapter.
Alexander Britcher	Alex Britcher is a third-year pharmacy student at the University of Maryland School of Pharmacy (UM SOP). He is interested in pursuing a career in regulatory affairs of health systems.
Ankit Gandhi	Ankit Gandhi is a second-year pharmacy student at the University of Maryland School of Pharmacy. He is interested in transplant medicine and regulatory affairs. During his time at school, he has been actively involved in American Pharmacists Association Pre-pharmacy Mentorship Program and Academy of Managed Care Pharmacy student chapter. He is currently involved in transplant research with physicians from the University of Maryland Medical Center.

School	**University of Rochester**
1st Place Team	**"Simple English Explanation Directive (SEED)"** **Making clinical trial results more accessible and functional**
Team Member	Bethany Lennox
Presentation Abstract	Since the Plain Writing Act of 2010, the FDA has used "clear, concise, well-organized" writing in their publications, making information about their services and requirements easy to understand and accessible to the general public. However, this practice has not extended to information published about clinical trials on clinicaltrials.gov, and their technical language can alienate individuals not familiar with complex terms about a condition or disease. The Simple English Explanation Directive helps to overcome this comprehension barrier by requiring a cover page document for each trial submission outlining its purpose, subject demographics, adverse events, results, and other important details using a Basic English vocabulary. This document, its subsequent updates, and feedback on these documents' efficacy will help readers grasp the vital details of a clinical trial regardless of their education level or medical knowledge.
Team Member Bio	
Bethany Lennox	Originally from Delaware, Bethany earned her Bachelor of Science in biomedical engineering from the University of Rochester in 2016 with a concentration in biosignals and biosystems. She is now pursuing her Master of Science in biomedical engineering at the University of Rochester through the Center for Medical Technology and Innovation, an intensive program about developing medical devices and navigating the medical device industry. Her current partnership with the Anesthesiology Department at Strong Memorial Hospital is focused on improving epidural procedures by confirming needle placement in the epidural space using visual and pressure-based methods.

School	**University of Rochester**
2nd Place Team	**"3-Defining Patient Matched Implants"** **A streamlined process to test 3-D printed personalized implants**
Team Members	Kerry Donnelly and Brittany Garrison
Presentation Abstract	A quality systems approach is needed to streamline the process of validating the integrity of an emerging technology, individual patient-matched 3D printed implant systems. The proposal specifically aims to introduce an alternative approach to the current method used in additive manufacturing to ensure implants are safe for implantation. Usually test coupons, which are a piece of material proven to represent the geometry of the final product, are used to ensure that each batch of a 3D printed product has the appropriate mechanical properties. We believe that this is insufficient for patient-matched implants since there is new geometry introduced for every implant. Instead we proposed the 'I-MATE' system. First, images are taken and the implant is designed to match (Image), then the implant is modeled and tested using computer software to determine the weakest component (Model), next the weakest component is assigned and duplicated in the same print as the final product (Assign), the duplicated component is destructively tested (Test), and the results are evaluated to decide whether to accept or reject the product (Evaluate). This improved system ensures safety and effectiveness of patient-matched implants and will also address ambiguity of current FDA guidance documentation surrounding 3D printed medical devices.
Team Member Bios	
Kerry Donnelly and Brittany Garrison	Brittany graduated from the University of Rochester (2016) with a bachelor's degree in Biomedical Engineering and a concentration in Biomechanics. Kerry is a graduate of Binghamton University (2016) with a bachelor's degree in Biomedical Engineering and a concentration in Biomedical Devices and Instrumentations. They are now pursuing master's degrees in Biomedical Engineering at the Center for Medical Technology and Innovation (CMTI) at the University of Rochester and are members of the Orthopaedics team. The team is currently working to develop and patent a device to solve spinal needs surrounding pedicle breach detection during Posterior Instrumented Spinal Fusion procedures.