

**University of Maryland 2021 America's Got Regulatory Science Talent Competitions
Presentation Abstracts & Student Biographies**

University of Maryland	
1st Place Team	"PrescripChain" A modern-day application solution for post-marketing surveillance
Team Member Members	Delaney McGuirt, Sona Ghorashi, Richard Lee, Amie Lette, Varsha Pradhan, Amanda Summers
Presentation Abstract	The FDA has identified as a priority to "improve and streamline clinical and postmarket evaluation of FDA-regulated products." Current post-marketing surveillance infrastructure, including MedWatch, FAERS, SRP, and VAERS, suffers from cumbersome workflow, lack of patient and provider awareness, and delays in information. Of note, of the over two million adverse events reported in 2020 (as of March 23, 2021), only approximately 3.8% were voluntarily reported through MedWatch. PrescripChain addresses the FDA's priority by providing a mobile app for adverse event reporting that improves upon current post marketing surveillance systems. PrescripChain is novel in its use of blockchain technology which allows for automatic, bench-to-bedside tracing of the entirety of a pharmaceutical's lifespan while providing enhanced data security and privacy. Its easy-to-use interface and integration of 2D barcoding streamlines patient and provider event reporting. Ultimately, PrescripChain enhances patient safety, reduces provider reporting burden, and increases access to real-world data for regulators.
Team Member Bios	
Delaney McGuirt	Delaney McGuirt is a second-year student pharmacist at the University of Maryland School of Pharmacy (UMSOP). Prior to pharmacy school, she worked in clinical research in a translational cardiac catheterization lab at the National Institutes of Health (NIH). At UMSOP, she currently serves as President-Elect of the Phi Lambda Sigma (PLS) Pharmacy Leadership Society, Vice President of Policy and Advocacy for APhA-ASP, and Grassroots Advocacy Chair for AMCP. Delaney also works as a Graduate Student Research Assistant with the PATIENTS Program in the PHSR department at UMSOP, where she engages in patient-centered outcomes research. She is currently collaborating on a research project with UMSOP and the FDA evaluating bulk drug substances nominated for use in compounding by outsourcing facilities. Her interests include a clinical specialty in cardiology with an ultimate career in healthcare policy and advocacy.
Sona Ghorashi	Sona is a second-year student pharmacist at the University of Maryland School of Pharmacy (UMSOP) and a graduated MD from Iran. She currently works as a pharmacy intern at The Johns Hopkins Hospital. Previously, she collaborated with different teams of physicians and scientists to co-author articles exploring antibiotics, chemotherapies, and hormonal therapies. Currently, she is involved in a multi-center research project investigating medical and medication-related needs in Covid-19 ICU survivors. She currently serves as President-Elect of the UMSOP chapter of American College of Clinical Pharmacy (ACCP), Director of National Engagement of the Industry Pharmacists Organization (IPHO), and Student Ambassador for the UMSOP Career Navigation Program. Her future career interests lie in clinical and patient-oriented pharmacy.

Richard Lee	Richard Lee is a second-year student pharmacist attending the University of Maryland School of Pharmacy (UMSOP). He previously earned a B.S. in Public Health Science at the University of Maryland School of Public Health. He is currently employed as a pharmacy intern at CVS and a Pathways Student Trainee (Scientific) at FDA (organizational breakdown: CTP/OCE/DEM). He is currently the President-Elect of the Student Section of Maryland Public Health Association (SMdPHA) and is a research assistant conducting epidemiological research of social determinants of health to support evidence-based practice as part of UMSOP's Data to Action Research Team (DART). Upon graduation, he hopes to gain employment at a regulatory agency in a position that will align his interests in public health and pharmacology.
Amie Lette	Amie Lette is a second-year student pharmacist at the University of Maryland School of Pharmacy (UMSOP) and an incoming Intern at Novartis Gene Therapies. Prior to pharmacy school, she worked in preclinical drug development at Inotiv Biopharmaceuticals. Amie is involved with Phi Lambda Sigma (PLS), Academy of Managed Care Pharmacy (AMCP), and the Student National Pharmaceutical Association (SNPhA). Additionally, she conducts health economics research regarding COVID-19 with the PHSR Department at UMSOP and patient-centered outcomes research with PHSR, FDA and the National Health Council (NHC). Outside of school, Amie works as a pediatric Intern and Research Assistant at The Johns Hopkins Hospital and a Market Research Analyst for N&F Ventures, with a research focus on medication therapy management. Amie aims to transform healthcare into a value-based system that reshapes patient's lives, drug development, and commercialization.
Varsha Pradhan	Varsha is a first-year MS student in the Regulatory Science Program at the University of Maryland School of Pharmacy. Based in India, she has completed her Ph.D. in Pharmaceutical Sciences. She has experience working in both the production and formulation development of various drugs. Her current work in the regulatory field involves the registration of medical devices. She is passionate about addressing challenges in paediatric medicine which led her to become the Secretary of Society for Paediatric Medicines & Healthcare Initiative established in India and partake in collaborative projects with the European Paediatric Formulation Initiative (EuPFI). In the future, she would like to contribute significantly in the field of drug regulation in India through pharmacy education.
Amanda Summers	Amanda Summers is a second-year student pharmacist at the University of Maryland School of Pharmacy (UMSOP). She is currently serving as SGA Historian, AMCP school chapter Treasurer and Fundraising Chair, Maryland Pharmacy Coalition student committee member, and Career Navigation Ambassador at UMSOP. Amanda also virtually tutors students in the surrounding Baltimore area through the student organization "A Bridge to Academic Excellence." She is currently involved in health economics and outcomes research surrounding chronic lymphocytic leukemia with the Pharmaceutical Health Services Research (PHSR) department at UMSOP. Amanda is interested in pursuing a career in managed care or the pharmaceutical industry after graduation.

University of Maryland	
2nd Place Team	“Braille-iant”
Team Members	Lauren Correia, Minseok Han, Nathan Feeley, Yididya Hambissa
Presentation Abstract	“Braille-iant” would improve visually impaired persons’ accessibility to prescription information by providing auxiliary prescription labels with clear Braille overlay. This project idea was inspired by a patient consultation and an American Foundation for the Blind survey, and aims to bring increased autonomy, accessibility, and medication safety to visually impaired people.
Team Member Bios	
Minseok Han	Minseok (Joey) Han is a 3rd-year PharmD student who is also pursuing an MS in Regulatory Sciences at the University of Maryland School of Pharmacy. His main goal is to be a pharmacist who contributes to bringing innovative changes in the pharmaceutical field. He has been consistently involved in different organizations/events/internships to gain experience and expects to explore more through his APPE rotations this upcoming summer.
Lauren Correia	Lauren Correia is a third-year pharmacy student at the University of Maryland School of Pharmacy who is interested in public health policy and mitigating health inequities. She is highly motivated to continue fulfilling this role as a pharmacist by serving as an easily-accessible healthcare professional and extending patient-specific medication therapy management services to those of all backgrounds.
Nathan Feeley	Nathan Feeley is a 3rd year student at the University of Maryland School of Pharmacy currently pursuing a PharmD degree in hopes of becoming a community pharmacist. He currently works at Kaiser Permanente as a pharmacy technician. Previous to UMSOP, Nathan obtained a Bachelor's Degree in Biological Science from UMBC.
Yididya Hambissa	Yididya Hambissa is a third-year pharmacy student at the University of Maryland School of Pharmacy who is interested in pursuing a career in the pharmaceutical industry post graduation. After obtaining a bachelor's degree in pharmaceutical science from The Ohio State University, Yididya joined GenenTech Pharmaceuticals as a clinical scientist before pursuing her PharmD. She is currently interning at Windmill Therapeutics in order to further expand her industry knowledge.

University of Maryland	
3rd Place Team	<p>“ePROmetric”</p> <p>This is a proactive health monitoring mobile application for patient driven drug development that utilizes predictive analytics to provide personalized symptoms monitoring and risk management. This idea consists of a user-friendly patient interface that can easily relay data to providers, for example, efficient vitals and symptoms collection and wearable device activity.</p>
Team Members	Vaani Shah and Yash Mehta
Presentation Abstract	ePROmetric is a mobile application created for patient-driven drug development. This proactive patient health monitoring app is wearable-tech enabled and offers predictive analytics for personalization and risk management. Some features of this application include efficiently collecting vitals and symptoms as well as securely transmitting data to clinical trial teams in a FISMA compliant manner. This idea hopes to develop a standardized method of collecting patient-reported outcomes in order to incorporate patients' perspective into regulatory decision-making.
Team Member Bios	
Vaani Shah	Vaani Shah is currently a senior majoring in bioengineering at the University of Maryland, College Park. In the future, she hopes to revolutionize medicine by applying an engineering-oriented approach to problem solving in the fields of clinical diagnostics and therapeutics. Vaani will be attending medical school in the fall of 2021.
Yash Mehta	Yash Mehta is a senior pursuing a degree in aerospace engineering at the University of Maryland, College Park. He has a particular interest in mechanical design, testing, and structures. With experience in business and technical consulting, Yash will be joining Accenture Federal Services as a technology analyst in the fall.

Thank you to the Judges for this Univ. Maryland Regulatory Science Talent Competition event:

- Zane Arp, PhD, Director of the Division of Biophysics, Office of Science and Engineering Laboratories (OSEL), Center for Devices and Radiological Health (CDRH), FDA
- Roberta Glass, MD, Senior Medical Officer, Center for Drug Evaluation and Research (CDER), Office of New Drugs-1, Division of Psychiatry, FDA
- Barbee Whitaker, PhD, Office of Biostatistics and Epidemiology, Center for Biologics Evaluation and Research (CBER), FDA