2023 America's Got Regulatory Science Talent Competitions
Presentation Abstracts & Student Biographies

University of Maryland	
1st Place Team	**"Clinical Lab Scientists"** This team is made up of three second-year graduate students and one first-year graduate student from the department of Medical and Research Technology at the University of Maryland, Baltimore Graduate School. Their program director, Dr. Ivana Vucenik, served as their mentor. Given they do not have a background in pharmacy or related professions, but rather in laboratory science, these students gave a new perspective on improving regulations. They proposed using short-term regulations for laboratory developed tests as solutions for protecting the public from harm from start-up companies, such as Elizabeth Holmes's Theranos. These short-term regulations would be in place while the FDA's long-term solution, the Valid Act of 2020, is still being debated in Congress.
Team Members	**Marilyn Bekima, Rebecca Collins, Diran Dasi, Peyton Liebhardt**
Presentation Abstract	In recent years, there has been an increase in technology startups opening and operating laboratories. Some of these companies make exaggerated claims of revolutionizing medicine by introducing new technology that is not always based on sound science and uses data that has not been validated by peer review. These companies have been able to operate with little to no supervision by exploiting the loopholes and lack of regulation for laboratory developed tests (LDTs), the category under which they operate. We propose short-term regulations for LDTs that may be put in place to enhance patient safety while the VALID Act; legislation that will regulate laboratory developed tests long-term, is undergoing review in Congress.
Team Member Bios	
Marilyn Bekima	Marilyn Bekima is pursuing a master's degree in Medical and Research Technology with a concentration in Laboratory Management at the Department of Medical and Research Technology, University of Maryland Baltimore. She graduated Cum Laude with a bachelor's in Medical and Research Technology from the same university in May 2007. Prior to pursuing her master's degree, Marilyn was a Laboratory Operations Manager, managing three clinical laboratories in the Baltimore area. She is a certified quality auditor from the American Society of Quality and is a seasoned laboratory inspector.
Rebecca Collins	Rebecca Collins is a newly certified Medical Laboratory Scientist. She got her bachelors in 2022 from Stevenson University and she is currently working on her master's in research at University of Maryland Medical School. Her current job is at St. Joseph Hospital in the core lab. Besides winning first place at the America's Got Regulatory Science Competition, some of her recent accomplishments include the Orsia F. Young Leadership Award as well as an Excellency in Medical Laboratory Science Award from Stevenson. She is excited for the opportunity to present with her team today.

Diran Dasi	Diran Dasi is an ASCP certified Medical Laboratory Scientist with over 7 years of experience. Diran is on his last semester for his Master of Science degree with concentration in Laboratory Management. He is the Team Lead for the Automated Chemistry and Special Chemistry Laboratory at the SINAI Hospital of Baltimore and enjoys the role as it keeps him in-between supervisory and bench tasks. His passion is process improvement in the Laboratory profession and pride himself for being part of a team of graduate students, all Clinical Laboratory Scientists who competed and won the 11th annual America's Got Regulatory Science Talent Competition. Diran enjoys outdoor activities and occasions that bring people together.
Peyton Liebhardt	Peyton is in her final semester of working towards her Master of Science in Medical and Research Technology with a concentration in Laboratory Management at the University of Maryland Baltimore. Before moving to Baltimore from Cleveland to obtain her graduate degree, Peyton received her B.S. in Biology and minor in Psychology from the University of Dayton in 2021. She has multiple experiences in laboratories ranging from R&D, clinical research and clinical laboratories. Currently, Peyton works in the Core laboratory at University of Maryland Medical Center as a Medical Lab Scientist. Recently, she was part of the team that won first place at University of Maryland's "America's Got Regulatory Science" Competition, where she hopes that her experiences can shed light on regulations that could be in place to protect the public from potential harm from laboratory developed tests.

University of Maryland	
2nd Place Team	**"MagiKRx"** Brief description A web-based app that would generate real world evidence on drug effectiveness for diverse individuals who initiate newly approved Alzheimer's disease drug (Lecanemab). This app could be utilized in concurrence with RCTs and for future drugs approved for Alzheimer's disease
Team Members	**Godwin Okoye,John Rizk, Udim Damachi, Bernard Bright Davies-Teye**
Presentation Abstract	Alzheimer's disease (AD) is a neurodegenerative disease that mostly affects people 65 years and older. An estimated 6.7 million Americans aged 65 years or older are living with AD in 2023, and the prevalence is on the rise. Older Black Americans are twice as likely to have AD in the course of a lifetime compared to older Whites. Despite the high burden of AD, a definitive medication that helps to improve the cognition of individuals with AD has been lacking. Lecanemab was granted accelerated approval on January 6, 2023, based on an observed reduction in amyloid-beta plaque, a marker of AD. However, the RCTs imposed restrictive inclusion criteria, and only 2.3% were Blacks, despite the higher burden of the disease in Black patients. This drug is also priced at $26,500/patient/annum. Due to these limitations, post-marketing studies are needed to obtain full traditional approval. These confirmatory trials usually take many years to complete (up to 10 years), highlighting the need for more timely and real-time evidence regarding efficacy and safety. We propose our MaGiKRx App, a geospatial web-based mobile application, to provide real-time effectiveness evidence. Using validated PRO measures, MaGiKRx App will facilitate the collection of information on the demographic and clinical characteristics of those initiating Lecanemab, including patients who were under-represented in RCTs. The proposed app has several advantages, including that it: (1) Runs concurrently with confirmatory RCTs (2) Accelerates data collection (3) Increases patient diversity (4) Generates real-world evidence on effectiveness (5) Establishes a database for future research. One limitation of this app is that safety data will not be collected, largely due to the asymptomatic nature of the adverse events from the drug (e.g. intracerebral hemorrhages), which require MRI or other medical scan to detect. While this is a limitation of our App, alternative well-established adverse reporting tools such as FAERS can be used instead for this purpose. This app can be managed by the American Alzheimer's Association. MaGiKRX is user-friendly, protects patient privacy by adhering to Health Insurance Portability and Accountability Act (HIPAA) guidelines, and uses a validated Alzheimer's disease questionnaire (ADL-PI) that needs to be filled in once every three months, by the patient or direct caregiver.
Team Member Bios	
Godwin Okoye	Godwin Okoye is a pharmacist and a current graduate student in the department of Practice, Sciences and Health Outcomes Research at the University of Maryland, Baltimore. He is also a research assistant with The PATIENTS Program chaired by Dr. Daniel Mullins. Since 2021, He has been working as the project manager for the FDA One Health Initiative which seeks to develop research on health intersections between humans, animals and the environment. He has also worked on a couple of M-CERSI projects. He is an active member of ISPOR and Rho Chi

	honors society. His long-term goal is to pursue a career in the pharmaceutical industry where his skills as a health services researcher can be transferred to help with data driven patient centered outcomes research and real-world evidence generation.
John G. Rizk	John G. Rizk, BSPharm, MSc, is a pharmacist by training and a 2nd year PhD Student in Pharmaceutical Health Services Research at the University of Maryland, Baltimore, School of Pharmacy. He holds a master's degree in Regulatory Science from Arizona State University. His research interests are in pharmacoepidemiology and drug safety, health disparity research, health policy, pharmacotherapy, regulatory science and clinical trials. John is currently a graduate research assistant with Dr. Danya Qato (Associate Professor at the University of Maryland Schools of Pharmacy & Medicine), where he assists with M-CERSI projects and other projects. John is a member of the Rho Chi Honor society. He has published several papers in peer-reviewed journals.
Udim Damachi	Udim Damachi, Bpharm, MSc, is a pharmacist and a 3rd year Ph.D. student at the department of Practice, Sciences, and Health Outcomes Research at the University of Maryland, Baltimore, School of Pharmacy. She holds a master's degree in health outcomes from the University of Cincinnati, Ohio. Her research interests are in pharmacoepidemiology, drug safety, and medication utilization trends, particularly in chronic diseases. Her current research focuses on the use of cardiotoxic cancer treatments and their long-term effects on cancer survivors. Her goal is to improve clinical health outcomes and inform health policy decision-making by conducting research that provides real-world evidence and insights into the benefits and harms of medications in different populations. Udim is currently a graduate research assistant at the University of Maryland where she assists with FDA-funded projects and other pharmacoepidemiologic research projects. She has co-authored several abstracts and publications in drug utilization, safety, and effectiveness research.
Bernard Bright Davies-Teye	Bernard Bright Davies-Teye, MD, MPH, is a Physician by training and 4th-year Ph.D. Candidate in Pharmacoeconomics at the University of Maryland Baltimore (UMB). His research interests include utilizing advanced quantitative and qualitative methods, in Pharmacoeconomics and Pharmacoepidemiology, to generate real-world evidence (RWE) to inform healthcare and health technology assessment (HTA) decision-making to improve health outcomes. Presently, Bernard Bright works at Pharmaceutical Research Computing (PRC), UMB, as the project manager for the National Cancer Database (NCDB) bladder cancer research project funded by Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc. In this role, he applies his advanced quantitative data analytic skills, project management skills, knowledge of the US healthcare system, over 10 years of clinical practice experience, and strategic problem-solving skills to oversee the bladder cancer research project. While in the Ph.D. program, and before managing the bladder cancer research project, he worked with the PATIENTS program at UMB, as the project manager for the FDA M-CERSI COVID-19 testing collaborative research project under the mentorship of C. Daniel Mullins, Ph.D., the Executive Director of the PATIENTS program. Prior to joining the Ph.D. program, Bernard Bright worked as a Municipal Director of Health Services for the Ghana Health Service (GHS), and the Greater Accra regional program manager for the Global Fund-sponsored tuberculosis program, GHS. In those roles at the GHS, he led the development and deployment of a geospatial web-based mobile application to improve the uptake and adherence to childhood vaccines provided by the Expanded Program on

	Immunization (EPI). Additionally, he led several implementation research, including the cost of illness (tuberculosis, cholera, and malaria) studies, which helped to improve disease-specific health outcomes. Bernard Bright was inducted into the Rho Chi Society, an Academic Honor Society in Pharmacy. He has received conference presentation awards, including the Bill and Melinda Gates Foundation award (2014), and has co-authored several peer-review manuscripts and abstracts in high-impact journals.

University of Maryland	
3rd Place Team	**"NociRx"** With the focus on the issue of higher incidence of Adverse Drug Events (drug-drug interactions) in the geriatric population, we are highlighting the ADEs between over-the-counter analgesics and the prescription drugs a patient is currently taking. The proposed solution is a geriatric patient-friendly app that can help identify a safer over-the-counter analgesic with regards to the patient's current prescription medications. This app will determine a possible drug-drug interaction and its severity. If there is a severe drug-drug interaction, a message will prompt that will tell the patient to contact their pharmacist or prescriber before taking the analgesic. The app will incorporate age-friendly features such as a talking tool (text-speech) and a font toolbox to assist the geriatric patients in navigating the app.
Team Members	**Mehak Muneer, Naiha Muneer, Nana Esi Bray, Urooba Ali**
Presentation Abstract	Polypharmacy significantly increases the risk of drug-drug interactions and potentiates the likelihood of developing adverse drug events. The geriatric population in the United States is highly prone to polypharmacy and its risk. In addition to the simultaneous use of multiple prescription medications, the geriatric population extensively uses over-the-counter (OTC) products. This primarily includes OTC analgesics due to the higher prevalence of pain symptoms experienced by older adults. The issue of polypharmacy is further complicated by using OTC medications, specifically analgesics, because of the lack of interactions that go unnoticed. This places the patient at an increased risk of developing adverse drug events that can potentially be lethal. Due to the nature of this population, it is essential to design a resource that caters to their needs and abilities to maximize the effect. NociRx is an age-friendly app targeted toward the geriatric population, designed to provide easy-to-understand information about drug-drug interactions between current prescriptions and OTC analgesics. This app allows the patient to add their current list of prescription medications, scan OTC analgesics, and identify whether a drug-drug interaction exists based on a message prompt. The app employs age-friendly features, like text-to-speech and font size tools, to ensure the patient has a rewarding experience maintaining their health. In terms of long-term applications, the app promotes using health information technology to enhance health outcomes within the geriatric population.
Team Member Bios	
Mehak Muneer	Mehak Muneer is a first-year student at the University of Maryland School of Pharmacy. She is a Co-Historian of the Student Section of the Maryland Public Health Association (SMdPHA) and a Programming Committee member of the Pediatric Pharmacy Association (PPA). As a certified pharmacy technician, she resolves dosage conflicts, potentially harmful drug interactions, insurance issues, and other matters to ensure patient safety. She plans to customize her Doctor of Pharmacy (PharmD) with a dual degree in MS Regulatory Science. Following graduation, she plans to pursue a non-traditional Federal Pharmacy Career Path.
Naiha Muneer	Naiha Muneer is a first-year PharmD candidate at the University of Maryland School of Pharmacy (UMSOP). She currently serves as a committee member on the American College of Clinical Pharmacy (ACCP)-UMSOP chapter's Council on Infectious Diseases as well as the publishing committee of Pediatric Pharmacy Association (PPA). As a first-year pharmacy student, she is excited to be exploring the variety of career paths in pharmacy, both traditional and non-traditional. She is particularly inclined towards clinical pharmacology and regulatory affairs and is working in a research group within PPA with the goal to analyze the decoded data

	from 2015-2022 in association with The KIDs List (*K*ey Potentially *I*nappropriate *D*rugs for pediatrics) to identify trends and patterns in the data using IQVIA. She also enjoys working with patients and pharmacists in community settings since it is important for patients to have someone there who can answer their questions and help them navigate the complex world of pharmacy regulations.
Nana Esi Bray	Nana Esi Bray is a first-year pharmacy student at the University of Maryland School of Pharmacy (UMSOP). She graduated from Montgomery College with honors and has worked as a Pharmacy Technician for about three years. Currently, Nana works as a Pharmacy Technician at the University of Maryland Medical Center. She is also an active member of the Academy of Managed Care Pharmacy (AMCP) and the Student National Pharmaceutical Association (SNPhA). Nana is passionate about improving health outcomes and serving the underserved; she hopes to pursue a residency or fellowship after graduation.
Urooba Ali	Urooba is a first-year pharmacy school student at the University of Maryland, School of Pharmacy (UMSOP). She is currently a member of the Student Chapter of the Maryland Public Health Association (SMdPHA) and the Industry Pharmacists Organization (IPhO). Previously, she attended the University of Maryland, College Park where she graduated with a B.S. in Public Health Science and Minor in Spanish Language, Culture, and Professional Contexts. She is a Certified Pharmacy Technician and has worked as a pharmacy technician at Weis Pharmacy for a little over 2 years and has experience interning and volunteering in a research and hospital setting. She is a strong advocate for promoting health equity. This was partly demonstrated by her role as a Refugee Caseworker Intern at the International Rescue Committee (IRC) in 2021. Urooba hopes to carry her passion for public health throughout her career as a pharmacist. Along with pursuing her PharmD, Urooba hopes to pursue a Master's in Regulatory Affairs as a Dual Degree to help further her pharmaceutical interests in industry. She aspires to implement her public health passion as a profession in the pharmaceutical industry field.