

The Food and Drug Administration's (FDA's) 2015 ORSI Science Symposium
April 27, 2015
12:00-1:00 p.m.

America's Got Regulatory Science Talent Competition Winners

- 12:00 pm **Introduction**
Dr. Khaled Bouri – ORSI, FDA
- Welcome Remarks**
Dr. Stephen Ostroff – FDA Acting Commissioner
- Overview of Competition**
Dr. William Bentley – University of Maryland CERSI
- 12:05 pm **University of Rochester Talent Competition**
Introduction by Dr. Scott Steele and Dr. Joan Adamo – University of Rochester Medical Center
- Winning Team: “[Gene-ius](#)”- *Genome Database in Clinical Trials to Innovate Personalized Medicine***
Corey M. Hoffman
- 12:20 pm **University of Maryland Talent Competition**
Introductions by Dr. William Bentley – University of Maryland CERSI
- 3rd Place Team “[New Generation Regulation](#)”:** *Linkage of Instructional Videos to Medical Devices*
Benjamin Wu, Sophia Ma, Kenneth Doan
- 2nd Place Team “[One Correction](#)”:** *Making Drug Information More Accessible*
Emmanuel Ventura, Kumaran Ramakrishnan, Kevin Lei, Pragya Shrestha, Bob Pang, Joyce Yu
- 1st Place Team “[PHSRegulators](#)”:** *Mobile Application Conveying Safety Information to Communicate Risks of Medications and Devices*
Bilal Khokhar, Priyanka Gaitonde, Elisabeth Oehrlein, Jan Sieluk, Maya Hanna
- 12:55 pm **Closing Remarks**
Dr. Stephen Ostroff – FDA Acting Commissioner
- 1:00 pm Photos of Winning Teams with Dr. Stephen Ostroff
Opportunity to Talk with the Winners about their Ideas

*Presenting students in **bold**

Presentation Abstracts – Regulatory Science Talent Competitions

School	University of Rochester
Subject	Winning Team: <i>“Gene-ius”- Genome Database in Clinical Trials to Innovate Personalized Medicine</i>
Winning Team	Corey M. Hoffman, MS
Biography	Corey Hoffman is a 3rd year graduate student in the Department of Pharmacology and Physiology at the University of Rochester Medical Center. Corey is performing his PhD research in the lab of Laura Calvi MD. His research focuses on investigating the mechanism of how Parathyroid Hormone activates osteoblastic cells to support hematopoietic stem cells in the bone marrow.
Presentation Abstract	<p>Sequencing portions of the human genome provides a reference point for identifying novel genetic biomarkers that could be used in personalized medicine. Identifying these biomarkers earlier in drug development, such as during clinical trials, could aid in drug safety by identifying and targeting patient populations. To address this, clinical trials currently using sequencing would be required to deposit sequences from patients in their studies into a curated database. Sequences could be compared between patients that had positive, negative, or no response in the trial. Differences between these groups could yield genetic signatures (either mutations or polymorphisms) that would be associated with degree of response to treatment. Genetic mutations and polymorphisms have previously been used to identify patients that are less responsive to therapy in leukemia(1) and cardiovascular disease(2). Sequences could be further investigated from a basic science standpoint, to determine what their biological function is (RNA coding, protein coding, regulatory DNA sequence etc.). From a more focused standpoint if a novel drug is being investigated, Cytochrome P450 (CYP) genes involved in that drugs metabolism could be investigated. Identification of polymorphisms in these genes could identify patient populations that may not properly metabolize the drug, leading to varied responses and possible adverse events. Thus, this database would facilitate personalized medicine through identification of novel biomarkers in the form of genetic sequences.</p> <p>(1) Mendler JH, Maharry K, Radmacher MD, et al: RUNX1 mutations are associated with poor outcome in younger and older patients with cytogenetically normal acute myeloid leukemia and with distinct gene and MicroRNA expression signatures. J Clin Oncol 30:3109-18, 2012</p> <p>(2) Johnson JA, Liggett SB: Cardiovascular pharmacogenomics of adrenergic receptor signaling: clinical implications and future directions. Clin Pharmacol Ther 89:366-78, 2011</p>

School	University of Maryland
Subject	1st Place Team “PHSRegulators”: <i>Mobile Application Conveying Safety Information to Communicate Risks of Medications and Devices</i>
Winning Team**	Bilal Khokhar, Priyanka Gaitonde, Elisabeth Oehrlein, Jan Sieluk, Maya Hanna
Presentation Abstract	The FDA Regulatory Science initiative seeks to protect consumers through science and regulation of drugs. A few mechanisms highlighted by the initiative's strategic plan include identifying new ways for the FDA to better communicate risks of medications, and ways to capture data signals that detect adverse reactions from a new drug. In response to this strategic plan, we propose the creation of a mobile application that sends safety notifications and messages for particular medications. For instance, a patient will enter the medications that he or she is taking and the application will then send periodic messages regarding safety updates for the medication. Additionally, patients will be able to input adverse events associated with medications. This will allow the FDA to detect safety signals. This mobile application will help the FDA communicate with consumers in a meaningful and practical way.

School	University of Maryland
Subject	2nd Place Team “One Correction”: <i>Making Drug Information More Accessible</i>
Winning Team**	Emmanuel Ventura, Kumaran Ramakrishnan, Kevin Lei, Pragya Shrestha, Bob Pang, Joyce Yu
Presentation Abstract	We will be utilizing smart phones to help laypeople understand medication information in more accessible and easier-to-understand formats. Currently, the systems in place to provide patients with critical drug information use is antiquated. To combat patients' misinformation of important medication information, we propose a standardized platform that patients can use to get reliable information. This platform would present existing medication information using current technology and present it in a patient-friendly format.

School	University of Maryland
Subject	3rd Place Team “New Generation Regulation”: <i>Linkage of Instructional Videos to Medical Devices</i>
Winning Team**	Benjamin Wu, Sophia Ma, Kenneth Doan
Presentation Abstract	The variety of medical devices is constantly increasing and providers need to keep up with how to use each product. Devices can be complex or the patients perception of how to use the device compared to how it actually should be used can vary greatly. Misuse of medical devices such as inhalers can lead to thousands preventable hospitalizations and emergency room visits and billions in expenses. We propose that manufacturers begin to attach resources in the form of links or QR codes directly to the products. This initiative will be beneficial for all players. Patients will have access to tutorial videos to reinforce proper use of a product. This complements FDA's Safe Use Initiative and finally manufacturers benefits as patients learning how to use their product specifically will lead to brand loyalty.

** Biographies will be available online