

## Winner of URMCM's "America's Got Regulatory Science Talent" competition presents idea to FDA

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In some patients, acute myeloid leukemia strikes hard and fast. And in one subset of these individuals, researchers now know why: a mutation in their DNA which results in a more aggressive path for the disease.

With this knowledge, providers can potentially screen for this mutation, allowing them to treat the patients more intensively. The discovery was another success in the world of genome sequencing, which is being studied more and more frequently as scientists and physicians learn more about how variations in a person's DNA can affect how they respond to disease and medication. This approach is often referred to as personalized or precision medicine.



From left to right: Scott Steele, Ph.D.; Corey Hoffman; Stephen Ostroff, M.D.; Joan Adamo, Ph.D.

To further advance personalized medicine, Corey Hoffman wants all of the genomic data from trials utilizing genome sequencing to be accessible in the same database. This will allow researchers and scientists to easily expand on previous work, identifying and using these genetic markers to speed drug development and aid in drug safety by targeting specific populations

likely to respond to a given treatment. Hoffman's idea won URM's "America's Got Regulatory Science Talent" competition in February, and earned him a trip to Maryland, where he presented his database idea at the FDA's 2015 Office of Regulatory Science and Innovation Science Symposium.

"There are two potential outcomes that I could see," said Hoffman, a predoctoral student at URM, [told CTSI Stories in March](#). "The first is that you could screen a patient's genome so that when patients do respond well in a trial, maybe there's a genetic element they share.

"Secondly, certain individuals don't respond well to certain drugs because of how their body metabolizes the drugs... so you could screen people for mutations in their CYP gene to give indications for drug response, and who is and isn't a good candidate for a certain drug."

Hoffman, who was joined at the conference by University of Rochester's [Scott Steele, Ph.D.](#), and [Joan Adamo, Ph.D.](#), presented his idea to the FDA's Acting Commissioner, [Stephen Ostroff, M.D.](#) and other leaders and staff at the FDA.