

# America's Got Talent – Regulatory Science Style

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Veni Vidi Vici. It translates into English as “I came, I saw, I conquered.” It also happens to be the name chosen by one of the winners of the recently held *America's Got Regulatory Science Talent Competition*.



Dr. Ostroff and FDA staff discuss projects with students from the University of Maryland CERSI.

FDA recognizes that young scientists are our future. Now in its fifth year, *America's Got Regulatory Science Talent* is one of a number of initiatives FDA supports to encourage young scientists to pursue careers in the rapidly maturing field of regulatory science.

Each year, teams from the University of Maryland's Center of Excellence in Regulatory Science and Innovation (CERSI), and the University of Rochester's Clinical and Translational Science Institute (CTSI), compete by presenting their proposed solutions to a current challenge in regulatory science. The students identify the needs by consulting eight priority areas identified in [FDA's Strategic Plan for Regulatory Science](#).

Winners are decided by a panel of judges after evaluating each presentation for its quality and novelty, and the proposed solution's potential significance and feasibility. The winning teams come to FDA to formally present their ideas and have discussions with Agency scientists who are working in their project area. The event, held on April 12<sup>th</sup>, was sponsored by the Office of Regulatory Science and Innovation (ORSI) which is located in the Office of Chief Scientist. The winning teams certainly came, saw, and conquered.

This year's winners are:

## University of Maryland CERSI



Dr. Ostroff with the teams from the University of Maryland CERSI

1st Place Team – *Veni Vidi Vici*

*A high-visibility universal labelling system to communicate risks of hazardous drugs. Wonder if your prescription medication has some dangerous side effects that may be noted in “fine print” – or even nowhere – on the label? A universal symbol in red and yellow in a prominent place on the label is the “Veni Vidi Vici” Team’s solution.*

2nd Place Team – *Biomarker Boys*

*Platform to improve transparency for biomarker integration in Accelerated Approval pathway. Tackling a challenge experienced in this growing area of biomedical innovation, the “Biomarker Boys” created a form that facilitates transparent and structured integration of biomarkers into rare disease state drug development.*

## University of Rochester CTSI



Dr. Ostroff with the teams from the University of Rochester CTSI

1st Place Team – *Simple English Explanation Directive (SEED)*

*Making clinical trial results more accessible and functional.* Team “SEED” takes the incredibly complicated language that is often found when describing a clinical trial, and puts it in easy-to-understand form.

### 2nd Place Team – *3-Defining Patient Matched Implants*

*A streamlined process to test 3-D printed personalized implants.* The “3-Defining Patient Matched Implants” Team decided that a quality systems approach is needed to streamline the process of validating the integrity of individual patient-matched 3-D printed implant systems. Their proposal introduces an alternative approach to the current method used in 3-D printing to ensure implants are safe for implantation.

This competition reminds us that good science makes for good regulation. And it was great to see the outside-the-box thinking and innovative approaches these contestants took in addressing some of the challenges that FDA faces with the products we regulate. It’s also a good reminder that the future of regulatory science depends on training and education – and we cannot underestimate the importance of educational activities like these.

The innovative approaches from this year’s teams also show the power of collaboration, mirroring the collaborative approach FDA takes in leveraging the brainpower of our teams of scientists, engineers, statisticians, social and behavioral scientists, medical officers, communicators, and others. The teams from the University of Maryland and the University of Rochester demonstrate just how teamwork produces great results.

Congratulations to the schools for organizing the competitions and to the FDA mentors who encouraged the competitors. Each year the quality of the work improves and I’m certain it will benefit patients and consumers over the coming years. Please check out this year’s talent – including a presentation from a freshman at Maryland. Who knows? Maybe one of these students will be FDA Commissioner some day!

**To see the finalists present their innovative solutions to regulatory science challenges, visit [FDA’s America’s Got Regulatory Science Talent web page.](#)**

***Stephen Ostroff, M.D., is currently Acting Commissioner of the U.S. Food and Drug Administration***

[FDA flickr photos from FDA’s America’s Got Regulatory Science Talent](#)