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# Go west, FDA

*By C. Simone Fishburn, Senior Editor*

Whereas the **FDA**'s first two centers for regulatory sciences were focused on modernizing methods for evaluating drugs and devices and on building bridges with local academia, the agency now is looking at early drug development.

To do so, the FDA partnered with **Stanford University** and the **University of California, San Francisco** (UCSF) to create a new center focused on quantitative pharmacology that will give it a foothold on the West Coast.

But the FDA has not moved its attention away from later stage activities; it also announced a new center at **The Johns Hopkins University** that will work on improvements in clinical evaluation, social and behavioral science and food safety.

When the FDA laid out its strategy for advancing regulatory science in 2011, a core goal was to tap into academia to access fresh thinking about regulatory processes and deliver training opportunities for agency scientists. The strategic plan's overall aims were to develop new tools, standards and approaches for assessing safety, efficacy, quality and performance of products regulated by the FDA.[1]

As part of the plan, the agency launched its first two Centers of Excellence in Regulatory Science and Innovation (CERSIs) at the **University of Maryland, College Park** and **Georgetown University**. The former focuses on improving the review and evaluation of drugs and medical devices. The latter focuses on new methods for decision making, such as sharing research data and using bioinformatics.

The FDA's acting chief scientist Stephen Ostroff told *SciBX* that the first two CERSIs were pilot initiatives created close to home in order to facilitate direct interactions of FDA staff with academic scientists.

Now, the agency has included early drug development in its scope for innovation. In this second round, he said, the FDA solicited applications covering topics across the spectrum of drug development activities from better evaluation of early stage compounds to postmarketing surveillance. The result was the two new CERSIs at Johns Hopkins and Stanford-UCSF, which were awarded about $750,000 and $3.3 million by the FDA, respectively.

The Johns Hopkins CERSI's strategy for improving clinical studies and evaluation will involve collaborative training projects between scientists from the FDA and Johns Hopkins centers including the Center for Clinical Trials, the United States Cochrane Center, the Evidence-Based Practice Center and the Center for Drug Safety and Effectiveness.

The UCSF-Stanford center is the first in the CERSI network to be tasked with developing training programs and recommendations for improving preclinical safety and efficacy tests. In addition, the UCSF-Stanford CERSI will work on strategies for improving clinical trials and evaluation and on ways of harnessing diverse data sets through information sciences to accelerate new drug development.

Ostroff told *SciBX* that a key component of the CERSIs is the training of both FDA and academic scientists. One of the agency's priorities, he said, is to get on the map as a career destination for graduate students, who often know little about the FDA. In addition, the agency wants to raise awareness of regulatory processes among scientists who will go on to work in the biotech industry.

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> ***—Stephen Ostroff, Food and Drug Administration***

"We want to work with academic centers around the country to generate a pipeline of individuals who will get excited about the work at the FDA," he said. "We also want to educate future industry employees on how the FDA operates."

Kathleen Giacomini, one of the heads of the Stanford-UCSF CERSI, told *SciBX* that "the FDA doesn't really have a presence [in the Bay Area], but the climate of innovation is here—so they don't have a sense of what's going on here. We need an FDA face on the West Coast."

Giacomini is chair of bioengineering and therapeutic sciences at the **University of California, San Francisco School of Pharmacy** and cochair of the UCSF Center for Quantitative Pharmacology.

Russ Altman, a professor of bioengineering, genetics and medicine and director of the Biomedical Informatics Training Program at the **Stanford University School of Medicine**, will be the other head of the CERSI.

## Informatics for innovation

The Stanford-UCSF CERSI will use informatics and data-driven computer models to develop predictions about drug metabolism, toxicity and effectiveness in different disease models and diverse populations.

Ostroff told *SciBX* that the new CERSI "sits in an area with very sophisticated computational capacity and strong modeling and clinical capacity."

UCSF said in a press release that the partnership will combine its School of Pharmacy's expertise in pharmacology and therapeutics with Stanford's strength in bioinformatics.

Giacomini said that the industry is "using old tools for early toxicology and drug safety." She added, "The FDA talks about 'modernizing the toolkit', so we need to ask how we can use biomarkers, SNPs and so on in the regulatory framework to give us more reliable safety signals."

Giacomini said that one starting point will be to develop tools that can improve the transition to the clinic, for example, by creating better

predictions of the starting dose for first-in-human studies. That will require collecting data from the literature and making evidence-based recommendations on which biomarkers to follow or which endpoints to employ, she told *SciBX*.

Giacomini said that the CERSI would also like to address complex scenarios—such as progressive diseases for which information from diverse sources needs to be integrated. For example, she said, "how do you evaluate a multiple sclerosis therapeutic when the data come from numerous sources such as imaging and blood samples and the disease is progressing?"

Giacomini added that the Stanford group will mine available databases of electronic medical records and the FDA Adverse Event Reporting System to connect adverse events with biological signals that could be used in predictive modeling.

Ostroff noted that use of animal data from packages submitted to the FDA would require a separate agreement to be negotiated with the submitting party.

Giacomini said that the center also will focus on questions related to the slow timelines of drug development, such as how to develop three drugs that work together without it taking three times as long.

The CERSI's specific goals and metrics will be defined through a series of meetings between the FDA, Stanford and UCSF, Ostroff said. He does not expect the center's output to result directly in new FDA guidelines for preclinical safety and efficacy evaluation. Instead, he expects the work will build an information base to support the use of alternative methodologies in regulatory decisions.

In addition, Ostroff emphasized that the training component is a key aspect of what the CERSI will deliver. Giacomini said that the training could involve student exchanges and joint research projects between the FDA and the CERSI scientists from UCSF and Stanford.

Giacomini said that the **California Institute for Quantitative Biosciences** will also support the training provided by the CERSI. She added that the hope is that the center can help local biotechs develop better data packages for regulators by providing courses in regulatory sciences that would use FDA materials supplemented by Stanford and UCSF coursework. In addition, she said, visiting scientists from the FDA could help educate academics and entrepreneurs about regulatory sciences.

"We envision a rich exchange program between the FDA and UCSF and Stanford scientists, as well as a broad curriculum in regulatory sciences including drugs, biologics, devices and diagnostics," she said.

**Fishburn, C.S. *SciBX* 7(22); doi:10.1038/scibx.2014.632**
**Published online June 5, 2014**

## REFERENCES

1. McCallister, E. *BioCentury* **19**(38), A14–A17; Sept. 12, 2011

## COMPANIES AND INSTITUTIONS MENTIONED

**California Institute for Qualitative Biosciences**, San Francisco, Calif.
**Food and Drug Administration**, Silver Spring, Md.
**Georgetown University**, Washington, D.C.
**The Johns Hopkins University**, Baltimore, Md.
**Stanford University**, Stanford, Calif.
**Stanford University School of Medicine**, Stanford, Calif.
**University of California, San Francisco**, Calif.
**University of California, San Francisco School of Pharmacy**, San Francisco, Calif.
**University of Maryland, College Park**, Md.