

NCATS Is Out of the Bag

Congress funds NIH hub for catalyzing innovations in translational science

NIH has officially launched the National Center for Advancing Translational Sciences (NCATS). Composed primarily of existing NIH programs, the new spearhead for translational biomedical innovation has been funded for \$575 million in the fiscal year (FY) 2012 spending bill signed into law on December 23, 2011.

“Congressional support for NCATS marks a major milestone in mobilizing the community effort required to revolutionize the science of translation,” said NIH Director Francis Collins, MD, PhD. “NCATS aims to catalyze this effort.”

Most of NCATS is being transferred from NIH’s now-disbanded National Center for Research Resources (NCRR). Among the former NCRR components moved to NCATS, by far the largest is the Clinical and Translational Science Awards (CTSA) program, which supports a consortium of research institutions and was allocated \$487.7 million in FY 2012.

NCATS is precluded from supporting clinical trials past phase IIa, except in the case of certain rare diseases. NIH says that its overall ratio of funding basic versus applied research is not changing, and its Clinical Center, the nation’s largest hospital devoted entirely to clinical research, will not move to NCATS.

“This is the beginning of a new approach to research in translational medicine,” says Julian Adams, PhD, president of research and development at Infinity Pharmaceuticals and a member of a working group that advised Collins

on the formation of NCATS. “We are hoping for a sea change in thinking, not merely incremental technological advances.”

“NCATS will be a catalyst for the kind of work that’s needed to bridge the gap between discoveries and new medicines, new devices, and new diagnostics,” says William Chin, MD, executive dean for research at Harvard Medical School and another member of the advisory group. “It puts the imprimatur on a national mandate that we need to put together our best minds and work to break this logjam.”

The organization’s current funding level “is a good start,” Adams says. “It’s not nearly enough, but it helps set the tone and networks for the future.”

“We always knew that NCATS would be under-resourced,” comments Chin. The budget restrictions answer any questions about whether the NIH planned to launch a drug company, he adds.

“The goal of NCATS is to identify the bottlenecks in the drug development pipeline and develop new methods and tools to circumvent those bottlenecks; the goal is not to develop drugs themselves,” comments Kathy Hudson, PhD, NCATS acting deputy director, and NIH deputy director for science, outreach, and policy.

“NCATS will want to test its innovations using real therapeutic projects, but we anticipate those will be funded by others, including the other Institutes and Centers across NIH,” Hudson says. The NCATS CTSA program “provides infrastructure and resources for clinical trials across the entire spectrum, but is not the primary funding source for trials beyond phase IIa.”

Building NCATS as a focal point for translational research has been a key goal for Collins, who asked

the NIH Scientific Management Review Board to look at ways of improving NIH translational activities in May 2010. The board recommended the creation of NCATS in December 2010.

Outlining the rationale for the new organization in a July 2011 [commentary](#) in *Science Translational Medicine*, Collins, who headed the National Human Genome Research Institute from 1993 to 2008, notes that “the field of translational science today faces some challenges that are similar to those of the genomics field in 1990. For example, little focused effort has been devoted to the translational process itself as a scientific problem amenable to innovation... and as with sequencing of the human genome, many of the most crucial challenges confronting translational science today are precompetitive ones.” — *Eric Bender*

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