

THERAPEUTICS

US translational-science centre gets under way

Mission of newly formed NCATS is to dramatically speed up production of drugs and other therapies, but sceptics question agency's ability to deliver.

BY MEREDITH WADMAN

Scarcely a year after plans to establish it were made public, the National Center for Advancing Translational Sciences (NCATS), the newest branch of the US National Institutes of Health (NIH) in Bethesda, Maryland, is up and running. On 4 January the centre's 230 employees gathered for their first 'all-hands' meeting, at which they heard an exhortation from NIH director Francis Collins and his lieutenants about the importance of the centre's mission: finding ways to radically speed up the development of new drugs, devices and diagnostics.

"Patients suffering from debilitating and life threatening diseases do not have the luxury to wait the 13 years it currently takes to translate new scientific discoveries into treatments," Collins said on 23 December, the day President Barack Obama signed the law creating NCATS. Congress had for months expressed concerns that NCATS could infringe on the private sector, and that the NIH was rushing it into existence. But the critics relented, and Congress approved the US\$576-million centre on 17 December as part of a massive government funding bill.

The law creates NCATS from several existing NIH programmes — most notably, the Clinical and Translational Science Awards (CTSA; see table). In the new law, Congress directs the NIH to spend at least \$488 million on the awards in 2012. At the same time, it dissolves the National Center for Research Resources (NCRR), where the CTSA programme has been housed, and parcels out that centre's programmes to other parts of the NIH. NCATS will also administer a Cures Acceleration Network (CAN), authorized in the 2010 health-reform law and now funded for the first time under the new law. CAN, a competitive grant programme that will allow the agency to circumvent bureaucratic obstacles and push promising drugs forward, received just \$10 million, one-tenth of what Collins had requested. The minimal funding nonetheless means that the programme "can get up and running", says Margaret Anderson, executive director of

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ASSEMBLING THE PUZZLE

NCATS will be created from pre-existing NIH programmes. Their budgets give a sense of their relative scale.

Programme	Original NIH home	Funding in 2011
Clinical and Translational Science Awards	National Center for Research Resources (NCRR)	\$460.5 million (from NCRR); \$22.7 million (from NIH Common Fund*)
Components of the Molecular Libraries Program	National Human Genome Research Institute (NHGRI)	\$21.4 million (from Common Fund)
Therapeutics for Rare and Neglected Diseases	NHGRI	\$24 million (from all NIH institutes and centres)
Bridging Interventional Development Gaps (formerly called RAID)	NHGRI	\$15 million (from Common Fund)
Office of Rare Diseases Research	Office of the director	\$17.8 million
NIH-FDA Regulatory Science Initiative	Office of the director	\$2.7 million (from Common Fund)
Cures Acceleration Network	New	\$0 (\$10 million for 2012)

*The NIH Common Fund is a discretionary fund for short-term, trans-institute programmes, administered through the office of the director.

FasterCures, a think tank in Washington DC that actively supported the creation of NCATS.

But the new centre has its sceptics — some of whom have voted with their feet. At the NCRR, 26 employees left during 2011 while Congress was debating their centre's future — more than twice the turnover in 2010. The dismantling "was a complete shock and surprise", says Barbara Alving, the former NCRR director, who resigned in September.

Others say that Collins is naive to suggest that the NIH can fix bottlenecks in the drug pipeline when the far-better-funded pharmaceutical industry has failed to do so. Creating NCATS "is sort of like declaring the war on cancer", says one critic. "Now what? Getting drugs that work in people is a very hard thing to do." But Congress wants NCATS to steer clear of industry prerogatives anyway: the legislation establishing it pointedly insists that the centre should "not create duplication, redundancy and competition with industry activities". And Congress explicitly forbids it from sponsoring late-stage clinical trials.

In a separate report, Congress instructs NCATS to protect both the money and the mission of the CTSA programme, which funds recipients at 60 academic medical centres nationwide — even though the recipients' activities do not always overlap with the new centre's mission. The CTSA programme would comprise at least 80% of the NCATS budget. Lawmakers have instructed the agency to

enlist the Institute of Medicine to assess the CTSA's current mission, and to decide within 18 months whether changes are needed. Mark Lively, a biochemist at Wake Forest Baptist Medical Center in Winston-Salem, North Carolina, who served on the NCRR external advisory council, worries that, in the interim, NIH leaders will boost the rest of NCATS's budget by dipping into basic-science funding. NIH officials insist that this will not happen.

Meanwhile, at the top of the new centre's to-do list is finding a director. "We are thrilled with the applicants and are going to start interviews this month," says Kathy Hudson, acting deputy director of NCATS. ■

CLARIFICATION

The News story 'Last-minute wins for US science' (*Nature* **480**, 423; 2011) implied that the total US contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria is \$298 million. This is just how much the National Institutes of Health was set to provide in 2012, and which will now be given instead by the Department of State.

CORRECTION

The News story '2011 in review' (*Nature* **480**, 426–429; 2011) confused its melanoma treatments: 'ipilimumab' should read 'vemurafenib'.