A helluva town:
New York launches genome center to spur local biotech

Silent killer:
Researchers link synonymous mutations to disease

Year in review:
A look back at the biomedical highlights of 2011

Trial networks move beyond single-disease strategies

To facilitate multicenter trials, the US National Institutes of Health has long provided extramural funding to groups of clinical researchers investigating therapies for major diseases or organ groups such as asthma or kidney failure. The money for these disease-specific networks has historically gone toward establishing the infrastructure for trial investigators to consolidate data and research resources across geographically distributed sites, as well as toward annual meetings and training programs of collaborators. But networks focused on particular disease types or organ domains often suffer from a siloing of academic expertise. So, now, a new trend is afoot at the agency, as individual institutes aim to take a more interdisciplinary, multidisease approach to their clinical extramural programs.

The US National Institute of Neurological Disorders and Stroke (NINDS) is the latest institute to consider alternatives to the single-disease-network strategy. "We have over 400 diseases—some count even more—within our mission, so it's not feasible for us to have a network for each disease," says Petra Kaufmann, director of the NINDS's Office of Clinical Research. In an effort to bring down costs and to pool resources and know-how across all the disease areas that fall under the institute's purview, in October the NINDS unveiled its new Network for Excellence in Neuroscience Clinical Trials, referred to colloquially as NeuroNEXT.

With 25 participating clinical sites across the US, the seven-year, $84 million network is intended to support biomarker-informed, exploratory clinical trials for a wide range of neurological disorders affecting both children and adults—and to potentially supplant existing trial networks devoted to Parkinson's disease and stroke once the funding for those runs dry. "There seemed to be a need to share expertise between disease areas, and we wanted something that would respond flexibly to opportunities as they arose in a number of disease areas," says Kaufmann.

Unlike with previous networks funded by the institute, studies conducted through NeuroNEXT will go through a centralized institutional review board and share the same contract agreement forms, with both managed through an independent clinical coordinating center located at the Massachusetts General Hospital (MGH) in Boston. This should expedite trials moving from the planning stages to full participant recruitment, notes NeuroNEXT executive committee member Karen Marder, a neurologist at the Columbia University Medical Center in New York. "I don't know that any disease-specific network would be able to get that kind of buy-in as quickly," she says. The first NeuroNEXT-supported study will be a $1.8 million trial looking for biomarkers associated with spinal muscular atrophy, and NINDS is currently accepting applications for other projects.


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Networking event: Trialists team up.

But NINDS is not the only institute looking to expand the umbrella of its collaborative clinical trial effort. The National Institute of Allergy and Infectious Diseases (NIAID), for one, is restructuring its HIV/AIDS clinical trials networks to create an infrastructure that can also handle other infectious diseases. Specifically, the institute plans to launch a new network focused on drug-resistant bacteria and emerging infectious diseases once the existing HIV/AIDS network grants expire in 2013.

"It really is a realization that we've had a successful model with HIV, and we're trying to get that extended to the non-HIV infectious diseases," says NIAID director Anthony Fauci. The funding will be small at first—just $15 million per year, compared to $280 million for the HIV/AIDS networks. But "that's a good start," Fauci says. "We're building it up slowly, and we're hoping it's successful."

Cooperation is key

The US National Cancer Institute (NCI) probably has the most advanced multidisease network in the country with its Clinical Trials Cooperative Group Program, a $150-million-a-year effort that enrolled approximately 23,000 patients last year in trials run by some 3,100 institutions affiliated with ten independent networks. But responding to criticisms of crippling inefficiencies and severe underfunding (see *Nat. Med.* **16**, 632, 2010), this 56-year-old stalwart of the NCI is being streamlined to include fewer cooperative groups with broader remits. Last month, the institute's board of scientific advisors voted unanimously to consolidate the existing networks—many of which were highly specialized on particular types of cancer—to a maximum of four adult groups and one pediatric group. The institute also plans to boost funding by $25 million per year and to rebrand the program simply the NCI Clinical Trials Network.

"What we really need is not a series of individual groups that sometimes work together but a network that always works together," says James Doroshow, NCI's deputy director for clinical and translational research. "We think this will help in diminishing costs, but also errors."

Even with the Cooperative Group Program's historic problems, Walter Koroshetz, deputy director of the NINDS, credits the NCI with inspiration for the new NeuroNEXT initiative. Notably, the NINDS is borrowing a legal instrument used the by cooperative groups to facilitate partnerships with industry. Through 'cooperative research and development agreements', or CRADAs, pharmaceutical companies can collaboratively run trials involving their proprietary drugs with NeuroNEXT while retaining full patent rights and data confidentiality. "This CRADA mechanism is critical," says Koroshetz. "It enables the NeuroNEXT network to test the best therapies coming from both academia and industry… We couldn't do that before."

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