New NIH effort seeks to find ways to make trials run smoother

With multiple sites and complicated protocols, clinical trials do not always run as smoothly as desired. So the US National Institutes of Health (NIH) has created a new initiative to determine how researchers can maximize the use of electronic medical records and engage patients over the internet to improve these trials, all of which is designed to help bring down the spiraling costs of running a clinical trial.

The NIH launched the Health Care Systems (HCS) Research Collaboratory on 25 September, awarding seven researchers a total of $11.3 million in grants to consider everything from the most efficient means of recruiting participants for trials to best ways of designing an experiment and handling large amounts of data. "Although the clinical projects deal with distinct diseases, the overall goal is to develop the research methods and best practices that can be readily used," says Catherine Meyers, director of the Office of Clinical and Regulatory Affairs within the NIH's National Center for Complementary and Alternative Medicine, in Bethesda, Maryland.

For example, one of the grants went to internist Gary Rosenthal of the University of Iowa Carver College of Medicine in Iowa City. Rosenthal is investigating whether switching people from daytime to nighttime doses of antihypertensive drugs lowers the risk of heart attack—but the exact subject of the study isn't relevant to the HCS Research Collaboratory. The new grant is designed to help Rosenthal assess how best to identify prospective participants through electronic health records and obtain consent online. The award should also allow Rosenthal's team to design the experiment so that participants can report when they take the drugs and how they're feeling through a website. Researchers conducting clinical trials have made use of the Web for years, Rosenthal notes, but it has been a bit haphazard, lacking the unified protocol explaining best practices that this project hopes to establish.

The initiative also considers how pragmatic trials, which use information already collected in healthcare systems and run during the course of routine medical practice, can yield results comparable to those found under idealized trial conditions. That's the goal of Gloria Coronado, a grant recipient from the Kaiser Foundation Hospitals in Portland, Oregon. She's designing pragmatic studies to pinpoint who needs colorectal cancer screening and to analyze which methods of encouraging people to get tested work best. Pragmatic trials are "cost-saving and more akin to what happens in the real world, outside of clinical trial settings," she says.

Susan Matthews

Spain sees worrying dip in research spending by drug companies

BARCELONA — Spanish pharmaceutical companies last year cut their investment in research and development for the first time in a decade, from €1.03 billion ($1.35 billion) in 2010 to €974 million in 2011, according to a survey of 49 companies published on 24 September by Farmaindustria.

"R&D has been cut because of the recession," says Javier Urzay, vice president of Farmaindustria, the trade organization representing the country's pharmaceutical industry, based in Madrid. "And the slashing of public pharmaceutical spending has reduced incomes."

The sector has been hit hard by the global financial crisis in the form of federal legislation to reduce the country's annual drug expenditures from €12.7 billion (the record reached in May 2010) to an expected €8 billion by the end of 2013. To make matters worse, these declines in spending come at a time when Spain's overall pharmaceutical market is contracting: it shrank by 6% last year—the worst performance among the five largest markets in Europe, according to the 2011 World Pharmaceutical Market Summary published this year by the New Jersey–based consulting company IMS Health.

The new Farmaindustria survey "may be a message to the government," says José Luis García López, a biotechnology expert at the Center for Biological Research in Madrid and a former advisor to the country's Ministry of Science and Innovation. He says that if the rewards for developing good drugs decline, companies will invest even less in research.

Guzmán Lozano

Falling capital: Madrid's cash flow problem.

Joan Guinovart, director of the Institute for Research in Biomedicine (IRB) in Barcelona, has not seen many research contracts cancelled. But public funding for biomedical research has suffered its part of the 34% cut applied to the government's research and development budget from 2010 to 2012. Experts note that the Consortium for the Support of Networked Biomedical Research (CAIBER), created by the government to carry on noncommercial clinical trials, has seen its annual budget shrink from €10 million in 2008 to €3 million in each of the last two years.

As an upshot, the cuts are pushing private companies and public research centers to work closer together than ever before. In June, for example, the Spanish National Cancer Research Centre in Madrid signed an agreement with the Swiss drugmaker Roche to develop early-stage ideas for anticancer medicines. And in September, Esteve, a leading Spanish pharmaceutical company, announced that it would move all its discovery and preclinical development laboratories to the Barcelona Science Park, home to the IRB and the National Centre for Genomic Analysis.

Michele Catanzaro

Correction

In the September 2012 issue, the article entitled "Controversial egg-producing stem cells promise better IVF" (*Nat. Med.* **18**, 1311, 2012) incorrectly stated the age range for OvaScience's first clinical trial as 35 to 42 and the anticipated time frame for commercial product launch as late 2013. The correct age range is 38 to 42, and the commercial product launch will be in 2014. The errors have been corrected in the HTML and PDF versions of the article.

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