

Pilot projects aim to ease access to clinical data

It can take many months for researchers to locate a sufficient number of eligible study participants for a clinical trial on a rare disease. Although databases listing volunteers from past studies and patients who have never been study subjects exist at universities and hospitals, investigators seeking to access such databases at institutions beyond where they work face bureaucratic obstacles—making it difficult to quickly identify volunteers with rare conditions.

With support from the US National Institutes of Health (NIH), a team led by Nicholas Anderson at the University of Washington aims to address this problem by extending a Harvard-based network of ‘anonymized’ patient information from hospitals to include additional medical centers beyond the Harvard University system, creating a one-stop shop for investigators seeking suitable study volunteers.

This project is one of three \$1.3-million contracts awarded by the NIH in January to build or expand databases of patient information for small-to medium-size clinical trials.

“Each of the informatics pilot projects seeks to reduce the burden on these researchers as they generate hypotheses, initiate studies and collect and analyze their data,” says Elaine Collier of the NIH’s National Center for Research Resources.

Isaac Kohane, co-director of Informatics for Integrating Biology and the Bedside (i2b2), a center for biomedical computing supported by the NIH, explains that i2b2 created software to facilitate researchers’ access to patient data. “We asked the question, ‘Can we use information that is a byproduct of routine healthcare for our studies without having to create a parallel clinical research [database]?’” he says.

Harvard researchers can currently access certain anonymized patient data from several hospitals affiliated with the university using the i2b2 system. Anderson plans to work closely with doctors beyond the Harvard hospitals to build a wider system that integrates anonymized demographic and diagnostic data from patients for researchers to search.

Anderson hopes the current project will shed light on how to design future interinstitution data-sharing systems. “If this [database] model doesn’t work out, I think we’ll know what it takes [to make such a system work],” he says.

The other two projects supported by the NIH awards will build or extend networks to

share certain information about people who have volunteered for biomedical studies. One of these, based out of Vanderbilt University, called the Research Electronic Data Capture (REDCap) system, aims to enhance a data-

sharing tool currently used by more than 30 institutions. The other will develop a program named Physio-MIMI to enable sharing of details pertaining to heart and genetic data.

Kirsten Dorans, New York

Pfizer to disclose financial ties

Following similar initiatives from drug companies such as Eli Lilly, Merck and GlaxoSmithKline last year, the pharmaceutical giant Pfizer announced on 9 February that it will publicly disclose its compensation of US clinical investigators.

The voluntary move comes as lawmakers are pushing for increased transparency of the financial ties between doctors and drug companies. In January, US Senator Charles Grassley of Iowa and others introduced the Physician Payment Sunshine Act of 2009, which would require all pharmaceutical, biotechnology and medical supply companies that receive financial support through Medicare, Medicaid or the State Children’s Health Insurance Program (SCHIP) to disclose compensation—both payments and nonmonetary gifts—given to physicians or medical practices.

Pfizer plans to disclose its compensation to doctors, clinical investigators and other

healthcare professionals for speaking engagements, consulting and clinical trials from 1 July 2009 and onward. However, although Pfizer will report compensations totaling more than \$500 a year, Grassley wants to require medical companies to disclose payments exceeding \$100.

Grassley is also working to expose potential conflicts of interest for researchers who receive US National Institutes of Health (NIH) grants. On 5 February, Grassley co-sponsored an amendment to the economic recovery bill that would require principal investigators who receive NIH grants over \$250,000 to report significant financial interests in companies supporting the work and explain how they would protect against possible conflicts of interest. The amendment was not included in the final bill that legislators passed, but Grassley will continue to pursue this issue.

Kirsten Dorans, New York

Survey gauges dual-use attitudes

Since the 2001 fatal anthrax letter mailings, concerns have increased in the US over so-called ‘dual-use’ biological research (research that could be misused to harm public health or national security).

In an effort to gauge US researchers’ knowledge and attitudes about dual-use research, the National Research Council and the American Association for the Advancement of Science (AAAS) surveyed AAAS members in the life sciences in 2007. On 5 February, the Research Council released a report of the survey’s results. Although the survey has limitations—including a low response rate—it yielded some of the first empirical data on US researchers’ views about these issues.

To the authors’ surprise, about 15% of the 2,000 respondents have taken action on their own—including abandoning

collaborations with overseas biomedical researchers—to try to avert misuse of research in the life sciences.

The finding worries Gigi Kwik Gronvall of the Center for Biosecurity at the University of Pittsburgh Medical Center. “In the larger sense of security, I don’t think it’s a good idea to break off collaborations,” Gronvall says.

About half of survey respondents agreed with increasing restrictions on access to so-called ‘select agents’, pathogens that pose a known public health risk. This response comes at a time when some government research facilities have stepped up regulatory control, such as the 6 February temporary suspension of research involving select agents at the US Army’s Fort Detrick infectious disease labs.

Kirsten Dorans, New York