Four models of clinical trial data sharing offered in new report

There is no hiding from the transparency movement. The pharmaceutical industry is feeling increased pressure to provide greater access to the data its clinical trials produce. Ultimately, the question now is not if it will share this data, but how—and with whom.

To that end, the US Institute of Medicine (IOM), an independent advisory body based in Washington, DC, held a two-day workshop last month to discuss an interim report that highlights four possible mechanisms by which scientists and trial sponsors can make information generated by clinical studies available.

Committee chair Bernard Lo, president and chief executive of the Greenwall Foundation in New York, describes the four models outlined in the 22 January draft framework as a starting point. The greater objective, he says, is to "focus attention on the specific issues that need to be resolved" in data sharing.

One mechanism proposed by the IOM panel is an 'open access' model in which all clinical trial data would be available to anyone: scientists and the public alike. Another would permit data access only to members of a scientific consortium or defined partnership. The third and fourth models would make trial information—either pooled across multiple data sources or from an individual entity, be it a company or academic institution—available only on a 'controlled access' basis.

Data dilemmas

The research community remains divided over which data sharing model will provide the best balance of advancing biomedical research while still maintaining the privacy of research participants and the competitiveness of drug companies.

"I think open access is best," says Steven Woloshin, co-director of the Center for Medicine and the Media at the Dartmouth Institute for Health Policy and Clinical Practice in Lebanon, New Hampshire. "Otherwise there is too much of a chance that [drugmakers] would selectively release information, which would undermine the purpose." Curtis Meinert, who studies clinical trial methodology at the Johns Hopkins Bloomberg School of Public Health in Baltimore, is less sanguine. "It is unwise to deposit trial data for use without assurance that users will not de-anonymize data," he says.

Complicating matters is the multinational nature of many clinical trials, which often involve researchers, sponsors and participants in multiple countries. "Different countries have different legal frameworks about intellectual property, informed consent, data privacy and antitrust [laws]," says Lo.

The optimal approach "remains to be determined," notes Robert Califf, director of the Duke Translational Medicine Institute in Durham, North Carolina. After a public consultation, the IOM expects to issue final recommendations before the end of the year. "This next period of 'trying out' different approaches by different organizations will be a chance to find the best approach for each type of data," Califf says.

Nicholette Zeliadt & Roxanne Khamsi

New data protection rules could harm research, science groups say

Unrest is stirring in Europe over a proposed amendment to the EU's draft General Data Protection Regulation that would prohibit researchers from using individual medical records for research unless explicit consent for that purpose has been given by patients. The policy, if implemented, would dramatically reduce the ability to conduct investigations involving data from disease registries and stymie cohort studies, which obtained more general consent from their participants years ago.

Given these concerns, a coalition of more than 40 medical organizations, led by the London-based Wellcome Trust, launched a campaign on 29 January to petition politicians to undo the proposed change when the draft regulation comes before the European Parliament in the coming months. As written, the amended regulation "narrows the scope of what a consent can be," says Alison Hall, program leader for legal and ethical issues at the PHG Foundation, a UK-based genetics and health policy think tank that is part of the coalition. "It says it has to be specific, informed and explicit, whereas before a broad consent would have sufficed."

Europe's legislative framework to unify data protection rules across the continent has been in the works for more than two years. It requires all individuals to opt in to have their personally identifiable information obtained and used by others. But the original draft regulation, published in January 2012, also included a provision that exempted scientific research studies from this mandate, the logic being that ethics committees already provide sufficient safeguards for research participants. This exemption is now under threat after a European Parliament committee introduced a proposal last October to dramatically limit the research exclusion for many types of medical data.

With that amended exemption headed for a vote, "we are all very, very concerned," says Elio Riboli, director of the School of Public Health at Imperial College London, who describes the regulation's potential impact on medical research as a "disaster." Riboli coordinates the European Prospective Investigation into Cancer and Nutrition (EPIC), a massive longitudinal study involving more than 500,000 participants across ten European countries that uses broad consent to allow researchers access to relevant data. He says it would be "nonsensical" if EPIC investigators had to send consent letters to each of the study's half-million-plus participants each time they wanted to study the data for a new research question. "Sixty-five million euros [$89 million] of investment to establish this project would be basically destroyed," he says.

Even if the restriction on medical research studies gets through the European Parliament, Magnus Stenbeck, an epidemiologist and expert in database infrastructure at the Karolinska Institute in Stockholm, expects the proposed regulation to face challenges in the more research-minded Council of Ministers, the other main branch of the bicameral European legislature. "I'm really quite optimistic that we will get reasonable legislation that will take away most of the obstacles that we felt was a danger," he says.

Elie Dolgin