European Parliament Approves Bill to Increase Clinical Trial Transparency

BRUSSELS—Researchers who do clinical trials in the European Union will have to make the results public under a bill approved by the European Parliament yesterday. In a sweeping vote held here yesterday, 594 members of the Parliament voted in favor of the plan, while only 17 voted against and 13 abstained.

The vote, which confirms an informal deal reached in December between Parliament and the European Union's 28 member states, is a victory for activist groups who want trials data out in the open. "This is fantastic," said Sile Lane from Sense About Science, one of the organizations behind the AllTrials campaign in the United Kingdom, in a statement after the vote. "It will mean that researchers will in future know about trials as they are happening and will be able to scrutinize results soon after their end."

Under the draft reform, trials carried out in the European Union must be registered in a central database, and a summary of results—positive or negative—must be uploaded within 1 year after the end of the trial. In addition, researchers must release a full clinical study report—which contains detailed information about the trial design and analysis, including patient-level data sets—if the medicine is submitted for marketing authorization, irrespective of that application's success. Academic researchers and companies would be fined if they don't comply.

Glenis Willmott, the British Labour parliamentarian who authored the Parliament's position, said that the reform will "set the global gold standard in clinical trial transparency." In a statement published before the vote, Willmott said the change can aid a similar push for greater disclosure of results at the European Medicines Agency, to "help ensure that data from old trials is also published."

The transparency push is only one part of a wider effort to improve the current rules, expedite procedures, and make Europe a more attractive location for clinical trials. While the commission's initial proposal avoided the sensitive issue of ethics committees, which vary widely across Europe, Willmott tried to clarify their role in authorization procedures.

The reform's practical execution will run into problems, predicts Adam Cohen, a professor of clinical pharmacology at Leiden University Medical Center and former member of the regulatory body for clinical trials in the Netherlands. In many European countries, national authorities and research ethics committees both examine the same trial applications, leading to “unnecessary bureaucracy” and “unclear accountability,” and giving too much leeway to ethics committees, Cohen wrote in *The Lancet* in 2012.

The new legislation does not address that but perpetuates a flawed system, Cohen tells *Science*Insider. “Do not fix the roof if the foundations are shaky,” he says. Cohen suggests the Dutch system, where a central body is responsible for accrediting and overseeing research ethics committees, would have been the model to follow.

The regulation now has to be formally approved by the Council of Ministers, which represents member states, and is expected to come into force in 2016 at the earliest.