

E.U. medicines agency relaxes data-sharing rules



Academics breathed a cautious sigh of relief when the European Medicines Agency (EMA) [announced yesterday](#) that it would soften controversial draft rules to open clinical trial data to public scrutiny. In particular, the agency says it will let researchers “download, save and print the trial data for academic and non-commercial research purposes.” A previous plan would have allowed them only to view data on their computer screens.

Last month, [researchers and the European ombudsman had slammed the agency's draft policy for data sharing as too restrictive and impractical](#). Today, they welcomed the announced changes but sounded a note of caution, as other controversial elements are likely to remain in the final text.

“This is a good move. It will mean researchers will be able to scrutinise, compare and share clinical trial information. Allowing researchers access to clinical trial information on-screen-only would have made their job impossible,” said Síle Lane, director of campaigns at the U.K. pressure group Sense about Science, [in a statement today](#).

But in an e-mail sent to *ScienceInsider* today, European Ombudsman Emily O'Reilly says she doesn't know if the agency has addressed her remaining concerns and will “carefully examine” the final text. The draft rules “imposed broad legal conditions” on data access and use, and “only allowed limited access to clinical trial data by redacting significant information,” O'Reilly says.

“The Ombudsman remains puzzled as to why EMA abandoned its original draft disclosure policy from 2012 and substituted it with a different draft policy, more in line with the pharmaceutical industry’s wishes,” her e-mail statement adds.

EMA spokesman Martin Harvey-Allchurch says the policy stems from a [lengthy consultation process](#). “We have listened and we have tried to come to what we think is a workable solution,” he says. The final text should be adopted in mid-July, before the new rules are rolled out in October.