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FEATURE

DRUG DEVELOPMENT

A failed attempt at collaboration

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The Mario Negri Institute for Pharmacological Research, a non-profit independent foundation, has withheld its involvement in an Innovative Medicines Initiative project that included clinical research and development of a product owned by GlaxoSmithKline.

Although we fully support the idea of further collaboration with industry, on this occasion the cooperation was not quite what we had hoped for. GSK set down the protocol for the clinical research in the partnership, and when we questioned some of the company's methodological choices—such as the comparator drug and sample size—it became clear that these were not open for discussion. A project agreement written by GSK and attached to the study protocol set out dozens of pages of rules and conditions that would effectively have made this a study controlled by GSK and not a collaborative study. GSK outlined a complex structure for governance of the trial with committees and boards and voting rules that effectively gave the drug company total control.

But for us, the biggest issue was around transparency. GSK wanted to retain the right to permit or refuse access to the patient outcome data and to give written approval for any independent publication of the data generated by the public-private partnership. That meant that we would have had to ask GSK's permission to access the data from our own trial and that GSK reserved the right to block publication of our analysis of that data at any time after the study was completed. This was hard to understand considering that GSK has recently made a public commitment in the *New England Journal of Medicine* to make clinical data available to anyone who wants to see them.[1]

Secrecy on clinical data implies undue exploitation of the rights of physicians and patients involved in the studies. This is even more inappropriate when publicly funded or independent non-profit institutions are contributing to the development of a drug and patients are generously volunteering to participate. Secrecy definitely sounds paradoxical when EU funds support the clinical research, as with IMI projects. The IMI's intellectual property policy recognises that "Ownership of the foreground [results, including data, know how, and information] belongs in the first instance to the participant(s) who generated it."[2] The UK's National Institute for Health and Care Excellence (NICE) is also surprised that transparency on research data about medicines is not universally applied and concerned by the implication of having to make appraisals of drugs without access to all relevant data.[3]

The Mario Negri Institute was ready to recognise GSK's ownership of the data. This is in line with the institute's ethical policy not to apply for patents on its discoveries and to publish all information for the benefit of the scientific community and the public. As a partner, the Mario Negri Institute asked only that the clinical researchers who had contributed subsets of data would be allowed to look at the overall raw data before publication. But there was no way the institute researchers could convince their colleagues and lawyers from GSK that this was reasonable.

The company insisted that it alone could decide who would ever see the raw data and for what purpose. No one would have had the right to publish anything about the outcomes of the study without the company's written consent. In the interest of patients and national health services we call for a change in the present IMI framework, where industry keeps interpreting public-private partnerships as "public duties and obligations" and "private privileges and advantages."

Competing interests: We have read and understood the BMJ policy on declaration of interests and have no relevant interests to declare.

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1 Nisen P, Rockhold F. Access to patient-level data from GlaxoSmithKline clinical trials. *N Engl J Med* 2013;369:475-8.
2 Innovative Medicines Initiative. Intellectual property rights policy. 2007. www.imi.europa.eu/sites/default/files/uploads/documents/imi-ipr-policy01august2007_en.pdf.
3 National Institute for Health and Clinical Excellence. Eighth report of session 2012-13, 16 January 2013. www.publications.parliament.uk/pa/cm201213/cmselect/cmhealth/782/78.2.pdf.

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