RESEARCH RULES

Red tape threatens noncommercial research in Europe

Proposed European Union laws that harmonize rules for clinical trials and aim to improve patient safety also threaten the future of noncommercial research in EU member states, say leading researchers on both sides of the Atlantic.

More than 2000 academics and scientists have signed a petition calling on the European Commission to repeal its Directive on Good Clinical Practice, which comes into effect in May.

The legislation aims to create a better environment for multicentre research within the union, but imposes heavy obligations on clinical trial sponsors. Heavy — and expensive, argues the Save European Research Campaign, which was coinitiated by the Breast International Group and the Irish Clinical Oncology Research Group (ICORG).

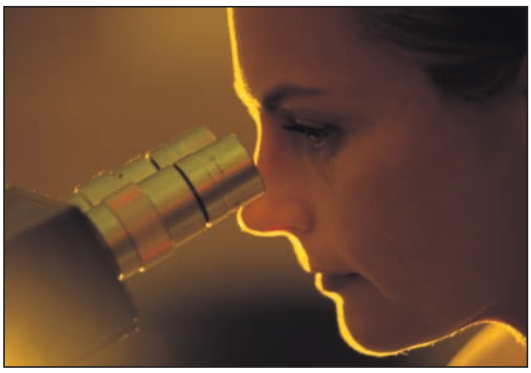
The crux of the problem lies in the increased obligations the directive imposes on the sponsor of a trial. This includes assuming the cost of all drugs and devices — even for routine noninvestigational aspects of the treatment. This means that an academic sponsor or nonprofit organization (rather than the health service in the UK) would have to pay for all the drugs a patient receives, including fully licensed drugs. Cancer research would be hit particularly hard because multidrug regimens are so expensive. A statement from Save European Research claims that trials that led to nonsurgical treatments for throat and breast cancer would not have been possible had the new laws been in place.

Kathleen Pritchard, a University of Toronto professor and board member of the Breast International Group, expressed concern that "groups like [ours] that are supported by grants, aid and charities won't be able to do trials in Europe any more and the only trials that will get done will be those that meet the agenda of the pharmaceutical industry."

The directive also places new administrative burdens on trial sponsors. Dr. Brian Moulton, spokesperson for the campaign and CEO of ICORG, says new rules on the relabelling of trial drugs will threaten research on cardiac disease. "In cardiac trials for example, all the aspirin would have to be purchased and relabelled as clinical trial drugs," he said. "Given the distribution costs, no single academic investigator could put together that type of study."

Pritchard says other academic research will be threatened because new rules on adverse effect monitoring will apply to all trials, not just those for new drugs. "The new level of bureaucracy will now be applied to any trial even when the drugs being used have been on the market for years but are being used in a different combination or a slightly different way." She added that many interesting studies on using existing drugs in different ways may be under threat because only academic researchers currently fund them.

Campaign organizers say that research previously carried out by a hospital consultant and a nurse will now require 2 consultants and 2 or 3 nurses just to cope with the paperwork.



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Only pharmaceutical companies will be able to afford to do research under a new EU directive.

Peter Sandler at the European Commission said the new rules "clarify how trials should be run, for example, who can participate or how they should be overseen. This should help patients participating and also, by having the same rules in different parts of the Union, encourage multicentre trials."

But Moulton rejects this view. "There are already a large number of pan-European studies underway. The idea that more regulation is going to bring more research doesn't make sense."

Even though the changes are only a month away, some researchers predict the European Commission will have to back down. The commission has also implied there is a glimmer of hope. "We don't want to put a brake on the excellent research done in the UK or elsewhere and we need to look carefully at the concerns being raised," said Sandler. — *Colin Meek*, Wester Ross, Scotland

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