

# COMMENTARY

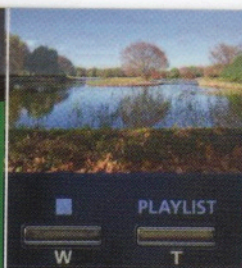
Sisters, brothers,  
bonds

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Media money  
for conservation?

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## LETTERS

edited by Jennifer Sills

### Rethinking Clinical Trials: Change Is Coming

IN HIS EDITORIAL "RETHINKING CLINICAL trials" (23 September, p. 1679), A. Grove suggests the provocative idea of using e-commerce software and data-mining techniques to conduct clinical trials and to streamline the process of making newer drugs accessible. There is no question that the present legacy system of three-phase pharmaceutical trials is time-consuming, overly expensive, and based on premises that will not apply to the new era of personalized medicine we seek to create. However, Grove's proposed system needs some fine-tuning.

Grove correctly leaves the safety issues to the FDA, but he does not address dosage issues, which should also be determined before distribution. He does not explore how virtual clinical research organizations of the

future would monitor issues of compliance and establish fair methods of measuring response. Replacing the heralded phase 3 trial with a self-administered trial would indeed save money and introduce the product much sooner to at least part of the potential market, but pharmaceutical companies would need some shielding of liability to protect them from the increased risks inherent in this plan. Because patients and third-party payers would undoubtedly see the new drugs as experimental, the pharmaceutical companies should be required to offer them at nominal cost.

That said, experimenting (carefully) is exactly what we should be doing. We need to abandon the fallacy of the control group, or the out-of-date comparative product, in favor of historical controls or some other method of assessing the disease. Moreover, no one who is seriously ill wants to be a

control. And as diseases are parsed into smaller and smaller subsets—when we find that each person's cancer is as individualistic as his or her face—then all illnesses may become orphans. The days of mass-market clinical trials may soon be over.

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