

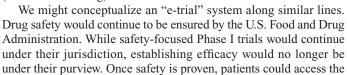
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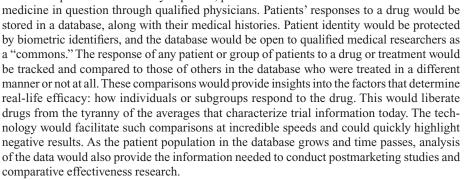
Rethinking Clinical Trials

THE BIOMEDICAL INDUSTRY SPENDS OVER \$50 BILLION PER YEAR ON RESEARCH AND DEVELOPMENT and produces some 20 new drugs. One reason for this disappointing output is the byzantine U.S. clinical trial system that requires large numbers of patients. Half of all trials are delayed, 80 to 90% of them because of a shortage of trial participants. Patient limitations also cause large and unpredicted expenses to pharmaceutical and biotech companies as they are forced to tread water. As the industry moves toward biologics and personalized medicine, this limitation will become even greater. A breakthrough in regulation is needed to create a system that does more with fewer patients.

The current clinical trial system in the United States is more than 50 years old. Its architecture was conceived when electronic manipulation of data was limited, slow, and expensive. Since then, network and connectivity costs have declined ten thousand–fold,

data storage costs over a million-fold, and computation costs by an even larger factor. Today, complex and powerful applications like electronic commerce are deployed on a large scale. Amazon.com is a good example. A large database of customers and products form the kernel of its operation. A customer's characteristics (like buying history and preferences) are observed and stored. Customers can be grouped and the buying behavior of any individual or group can be compared with corresponding behavior of others. Amazon can also track how a group or an individual responds to an outside action (such as advertising).





Today's e-commerce systems started small and took nearly 20 years to develop. Adapting this kind of capability to medical information would be a monumental undertaking. Initiating and overseeing it would be an appropriate task for the professional societies. There are encouraging signs, including a call in 2004 by the American Medical Association for public registries of drugs, as well as a proposal for trials that incorporate feed-forward mechanisms.* Another proposal would allow patients to choose between medicines whose efficacy has been determined in different manners.† There is also a suggestion to use control of pricing to encourage drug developers to move forward in a "progressive" trial design.‡ Ideas, however, are not enough. We need the professions to mobilize and take advantage of this enormous opportunity.

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