

Editorial**Artificial Intelligence and Patient-centric Approaches to Advance Pharmaceutical Innovation**

Since the start of this century, stunning advances in our understanding of the pathophysiology and genetic determinants of a host of diseases that currently lack adequate and effective treatments have opened the door to new avenues of biomedical innovation. In many cases, however, these scientific advances have not translated into the development of new and better medicines, especially for a number of diseases that take an exacting toll in morbidity and mortality, including heart disease, stroke, diabetes, obesity, and dementia.

Bringing a new drug to market requires more than a solid scientific rationale. Also needed are drug development expertise, access to resources to manufacture and investigate the molecule, ability to identify and enroll patients for clinical trials, substantial funding, and, to a degree, luck. These factors play an important role in determining the number and types of innovative new drugs reaching the marketplace.

So why has pharmaceutical innovation not kept pace with the remarkable increase in our scientific understanding of disease? One reason is the drug development process itself. Bringing a new drug to market is a lengthy, risky, and expensive endeavor. Current development benchmarks from the Tufts Center for the Study of Drug Development indicate that the average time spent in clinical development for new molecular entities is 7 years, ranging from 6.1 years for antimicrobial agents to 9.5 years for drugs to treat gastrointestinal conditions. Approval clinical success rates (ie, the likelihood that a drug candidate entering clinical testing will eventually reach the marketplace) for new molecular entities average 12%, and range from 23.9% for antimicrobial agents to a dismal 3.7% for cardiovascular drugs (in other words, >96% of cardiovascular drug candidates that start clinical testing will be terminated at some point during clinical development and will fail to reach the market). Ultimately, long development times combined with low probabilities of success translate into high development costs; the Tufts Center for the Study of Drug Development has pegged the total capitalized cost to bring one successful drug to the market, including the cost of failures, at \$2.6 billion, a 145% increase, in constant dollars, over a 10-year period.¹

Drug developers, increasingly, have identified clinical trial design and execution as critical determinants of overall drug development time, cost, and success.^{2,3} The introduction of a host of new tools—including artificial intelligence (AI), machine learning, and patient-centric initiatives—offer the potential to enhance decision-making at the clinical development stage by providing sponsors with more data and precision analytics than would be available using conventional drug development practices.

This special section of *Clinical Therapeutics* examines the adoption of these techniques and their potential impact on clinical trial execution and research and development productivity. In the first article, Lamberti et al⁴ present the results of a survey of pharmaceutical companies, which included in-depth interviews with drug development professionals, that sought to determine the extent to which AI has been incorporated into development programs, challenges with implementation, and perceptions about future utility. The authors determined that whereas there are notable challenges to its implementation, AI adoption is growing, and companies anticipate staff increases to manage its expanded use. This is reflected in the rapid growth in deal-making between pharmaceutical companies and contract providers that specialize in AI and machine-learning technologies.⁵



Kenneth I. Kaitin, PhD

In the second article, Anderson et al⁶ review the growing use of patient advisory boards within the biopharmaceutical industry, academic institutions, and various foundations and associations. These relatively low-cost, high-value boards serve the important function of gathering and amplifying patient feedback and input, enabling better approaches to clinical trial design and execution.

In the final article, Michaels et al⁷ assess implementation of up to 30 patient-centric initiatives across the biopharmaceutical industry, including patient organization landscape analysis, support of patient advocacy groups, use of patient advisory boards, and use of home nursing networks. The authors conclude that the use of these initiatives is robust and growing at a rapid rate.

For >50 years, drug development has remained a stubbornly time-intensive, risky, and expensive process. Despite remarkable gains in our scientific understanding of the basic mechanisms of many diseases, critical unmet medical needs persist. New tools to improve the design and execution of drug research and development, such as AI and patient-centric initiatives, offer the promise of speeding the development and availability of those breakthrough treatments that patients and their families have long sought.

Kenneth I. Kaitin, PhD

Tufts Center for the Study of Drug Development, Tufts University School of Medicine, Boston, MA, USA

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