

The Future of Cancer Drug Development: Advancements, Challenges, and the Transformative Role of AI

AI is revolutionizing oncology drug development, enhancing therapeutic identification and reducing approval times, but use of this tool must be carefully implemented to mitigate risks and ensure regulatory compliance.

The landscape of cancer research and drug development is constantly evolving, with groundbreaking advancements shaping the future of oncology treatments. Understanding not only the science but the regulatory concerns, legal challenges, and market climate for this industry is critical.

One of the most significant changes in recent years has been the introduction of artificial intelligence (AI) to drug research and development. This technology is revolutionizing how pharmaceutical companies operate, from initial drug discovery to post-marketing analysis. In the oncology field in particular, AI has the potential to make an important difference by helping to identify improvements to therapeutic agents and reduce approval times necessary to bring life-saving products to patients. However, its implementation includes potential risks, which must be mitigated to assure positive outcomes and acceptance by clinicians.



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Investments in Cancer Research and Drug Development

Investing in cancer research and drug development is particularly attractive due to the growing demand for innovative therapies and the potential for significant returns. The field of oncology has witnessed remarkable progress in recent years, with the emergence of targeted therapies, immunotherapies, and personalized medicine revolutionizing cancer treatment.

The global market for cancer immunotherapies is expected to grow exponentially in the coming years, rising from \$97.88 billion in 2023 to \$110.91 billion in 2024.¹ Recent innovations that utilize the body's immune system to target and destroy cancer cells, such as pembrolizumab (Keytruda; Merck), nivolumab (Opdivo; Bristol Myers Squibb), and cemiplimab (Libtayo; Regeneron), have shown success in treating various types of cancer by targeting a protein called PD-1, which is a checkpoint protein on immune cells that helps keep the cells from attacking other cells in the body. These checkpoint inhibitors have demonstrated significant efficacy in improving patient outcomes, with some combination therapies costing upwards of \$250,000 a year.

The oncology field is closely monitoring these advancements, as well as other immune checkpoint inhibitors (eg, CTLA-4 and PD-L1 inhibitors), CAR-T cell therapies, and next-generation sequencing technologies, which offer new avenues for developing effective treatments with fewer adverse effects (AEs).

AI has proved instrumental in supporting these efforts in many ways. For example, it can be used to help meet stringent patient recruitment requirements through the use of a digital twin: a virtual representation of a physical object that can be leveraged to better understand its behavior and reaction to stimulus. Digital twins utilized in clinical trials are virtual patients that reflect personal characteristics in a high degree of specificity, and can simulate patient outcomes in response to the drug treatment established in a clinical protocol. This can greatly enhance the patient recruitment effort by reducing the number of real patients needed for the study, the necessary time to conduct the trial, and the exposure of patients to deleterious AEs, as well as by helping to avoid the privacy issues that often arise with the sharing of clinical data. Additionally, AI can be used to analyze large amounts of data from clinical trials in order to identify the proper dosing, number of patients, and proper end points to be used to objectively determine if the therapy is beneficial.

However, while AI can transform the oncology landscape, its use in the drug development process can pose problems. AI learns from data, which may contain inherent bias or inaccuracy. Additionally, clinical data sharing, especially when associated with cancer, is highly sensitive and needs to be protected. Measures must be put into place that protect patients' privacy, mitigate risk for drug developers, and comply with both ethical and legal standards.

Regulatory Concerns in Cancer Drug Development

Regulatory concerns are a key consideration in cancer drug development. The process of obtaining regulatory approval for new cancer treatments can be complex and time-consuming, requiring rigorous clinical trials to demonstrate safety and efficacy. Regulatory agencies such as the FDA and the European Medicines Agency (EMA) play a critical role in evaluating new cancer drugs and ensuring that they meet stringent quality standards.

One of the main regulatory concerns in cancer drug development is the need for robust clinical data to support the approval of new therapies. Clinical trials must be carefully designed and

executed to generate reliable evidence of a drug's effectiveness and safety. Regulatory agencies may also require post-marketing surveillance to monitor the long-term effects of new cancer treatments and ensure ongoing patient safety.

In addition to patient recruitment, AI has the potential to increase the chances of success in protocol design and data analysis associated with oncology clinical trials. One current example of such an innovation is a program called SEETrials from Intelligent Medical Objects in Rosemont, Illinois, which extracts safety and efficacy information from the abstracts of clinical trials to guide clinical trial design.²

Regulatory agencies are increasingly focused on promoting innovation in cancer drug development while maintaining high standards of patient care. Expedited pathways, such as the FDA's breakthrough therapy designation and accelerated approval programs, have been introduced to facilitate the development and approval of promising cancer therapies, providing opportunities for faster access to innovative treatments for patients in need. However, increased concerns about use of AI in the drug development process may necessitate stricter guidelines and guard rails in order to maintain regulatory compliance and avoid additional pipeline hurdles.

Evolving Legal Challenges in Cancer Drug Development

In addition to regulatory compliance, intellectual property rights and patent protection are critical aspects of navigating the legal landscape of drug development. Both patent exclusivity and regulatory exclusivity play central roles in protecting the intellectual property of new cancer drugs. Patents grant companies the exclusive rights to market their inventions for a specified period: typically, 20 years from the priority date of an issued patent. Regulatory exclusivity, granted for drug approvals based on clinical studies conducted on a compound that has not previously been the subject of FDA approval, provides a time period wherein the FDA will not approve an abbreviated application for a bioequivalent product that references the proprietary product (5 years for small molecules and 12 years for biologicals). Patent litigation and challenges from generic and biosimilar manufacturers can pose significant legal hurdles for pharmaceutical companies seeking to bring new cancer treatments to market. Moreover, evolving legal frameworks and regulations in different jurisdictions present additional challenges.

The lengthy and costly approval process for new drugs, which can take up to 15 years and cost billions of dollars, poses a significant barrier to innovation. Regulatory agencies like the FDA play a crucial role in ensuring the safety and efficacy of new cancer treatments, but the process remains slow and cumbersome. Further, the high cost of cancer drugs for patients has raised concerns about affordability and access. Insurers and drug benefit plans are grappling with how to manage rising prescription drug costs, with some patients facing significant financial toxicity due to the high price of life-saving treatments.

Navigating the complex interplay of intellectual property protection, regulatory requirements, and cost barriers remains essential to ensuring that innovative cancer treatments reach patients while balancing affordability and market sustainability. AI has the potential to support that process by

creating greater efficiencies, which may ultimately have a significant impact upon pricing and accessibility of these lifesaving drugs.

Broader Predictions for the Cancer Drug Market

Looking ahead, the cancer drug market is poised for continued growth and innovation, driven by advancements in research, technology, and investment. The demand for new and effective cancer treatments is expected to rise as the global burden of cancer increases. Facilitating innovations through AI—with appropriate clinical and ethical standards—can accelerate drug development with more efficient testing and data analysis.

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