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Perspective

Drug Repositioning Challenges and Opportunities

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DESCRIPTION

Drug discovery is a time and capital-intensive, high-risk process in traditional drug development. Drug repositioning has become a popular strategy in recent years. Unlike traditional drug development strategies, this strategy is efficient, economical and risk-free. There are typically three types of approaches: computational, experimental, and mixed approaches, all of which are widely used in drug repositioning.

The Eastern Research Group (ERG) reports that it usually takes 10-15 years to develop a new drug. However, the average success rate of developing a new molecular entity is only 2.01%. The Food and Drug Administration (FDA) reports that the number of drugs approved by the FDA has declined since 1995. In addition, investment in drug development by the Pharmaceutical Research and Manufacturers of America (PhRMA) and others is gradually increasing. This indicates that the cost of developing new drugs will continue to grow. Therefore, there is an urgent need to find a new drug discovery strategy.

Drug repositioning, also known as old drugs for new uses, is an effective strategy for finding new indications for existing and highly effective, low-cost and risk-free drugs. Traditional drug development strategies typically include five phases: exploratory and preclinical, safety assessment, clinical study, FDA review, and FDA post-marketing safety monitoring. However, there are only four steps in drug repositioning: compound identification, compound acquisition, development, and FDA post-marketing safety monitoring. Due to the rapid growth of bioinformatics knowledge and biological big data, drug repositioning significantly reduces the time cost of the drug development process. On average, researchers need only 12 years to identify new drug targets and 8 years to develop a repositioned drug. In addition, the research and development investment required for drug repositioning is lower than with traditional strategies. Drug repositioning is breaking cost bottlenecks for many countries. It costs only $1.6 billion to develop a new drug using a drug repositioning strategy, compared with $12 billion for a traditional strategy. Therefore, drug repositioning creates opportunities for many countries to develop drugs with lower investment.

In addition to reducing investment and time costs, drug repositioning is also a low-risk strategy. Risk-reward diagrams are often used to describe the risk-reward relationship of an investment. Some researchers plotted a risk-reward plot to compare traditional drug development and repositioning strategies. Drug repositioning offers higher rewards with lower risks. Since the repositioned drugs have passed all Phase I, Phase II, and Phase III of clinical trials, their safety has been confirmed. In addition, some repositioned drugs may be marketed as molecular entities and are more likely to be brought to market when a new indication is discovered.

Challenges and opportunities

Traditional drug development strategies are expensive, prone to failure, and costly ventures. Therefore, recent drug repositioning has drawn attention and brings drugs out faster for clinical use. However, drug repositioning is a complex process that includes many factors such as technology, commercial model, patents, investment, and market demands. Although many medical databases have been established, selecting the appropriate approach to make full use of massive amounts of medical data is still a challenge. There is an urgent need to develop new approaches of drug repositioning. The Intellectual Property (IP) issue is another prominent issue that needs to be solved. For drug repositioning, the protection of intellectual property rights is limited. For example, several new drug-target-disease associations found by repositioning researchers have been confirmed by publications or online databases; however, the protection of intellectual property rights for these associations is very difficult due to the provisions of the law. Intellectual property issues prevent certain drugs from being repositioned into the market. Furthermore, some repositioning projects were forced to be abandoned, wasting time and money. It is necessary to develop a new business model because the traditional business model is a serial model and leads to the problem of overlapping investments.

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Opportunities come with challenges. The first example of drug repositioning was the accidental discovery of the 1920s. After about a century of development, other approaches have been proposed to accelerating the process of drug repositioning. For this reason, drug repositioning has been very successful. Massive machine learning algorithms have been introduced to improve the performance of drug repositioning in this scenario. In addition to the computational approach, an experimental approach has been developed that provides direct evidence of drug-disease associations such as: Target screening approach, cell assay approach, animal model approach and clinical approach. These approaches are reliable and credible. In recent years, increasing numbers of researchers have combined computational and experimental approaches to discover new indications for drugs, the so-called mixed approaches, and the results of the computational methods have been validated by biological and clinical trials. The mixed approach provides an opportunity for effective and rapid development of repositioned drug.

The generation of secondary patents provides researchers with the opportunity to discover new indications for existing drugs. Resolved IP issues have raised concerns in many countries as many relocation projects are carried out smoothly and inexpensively. For commercial models, parallel strategies can significantly improve the efficiency of drug repositioning. For example, multiple tests or studies are conducted for a candidate drug, reducing the time required to relocate the drug. From a market perspective, various diseases require new drug treatment and have potential economic benefits. Taking rare diseases as an example, there are more than 6000 rare diseases that need to be studied. However, only 5% of them have been studied. Rare diseases are a large market to explore.