

Unveiling Therapeutic Potential: Investigating Avenues for Drug Repurposing

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Abstract

Drug Repurposing opportunities arise from potential observations, discussions, and collaborations, including the development of different meaningful platforms for the identification of drugs and their potential targets and allow the accessing of compounds. Drug Repurposing is an approach that uses the existing approved/failed drug for novel clinical use. This approach has the advantage that the compounds have already undergone different drug discovery phases and have sufficient information related to safety, efficacy, formulation, dose, and potential toxicity. As a result, this strategy is gaining considerable attention in drug research because of its cost-effective and time-saving capabilities. In recent years many pharmaceuticals are utilizing this approach for their drug discovery and development program, in fact in the Covid-19 era, its utility increased by many folds.

Keywords: Repurposing; Drug; Clinical trial; Computational approach

Introduction

Drug development is a very challenging, complex, long running, and expensive process with a very low success rate. Lately, a significant decline has been observed in the number of drugs approved for clinical use. The high failure rate and high investments of the traditional drug delivery system urged us the way to look for an alternative. The most suitable one that emerged in this context was 'Drug Repurposing'. Drug repurposing has become a popular strategy in recent years. It can be compared to drug recycling [1]. It is an alternative drug development strategy whereby already approved drugs for treatment or management of some diseases and/or whose targets have already been located, are explored and exploited. The goal of repurposing drugs is to find ways to make use of already approved drugs or those that did not complete clinical trials to find new uses or indications. This strategy differs from the traditional drug development strategies in that it is efficient, economical, and riskless. This makes drug repurposing one of the most active areas in pharmacology and pharmaceutical chemistry in the last few decades.

Drug repurposing

'Drug repurposing' is an efficacious, successful, and innovative way to look for and bring about new targets or new indications of any drug that has already been approved by the FDA and that already exists or survives in the market. It is a novel strategy to discover new therapeutic uses for already known drugs, including approved, discontinued, shelved, and experimental drugs, by exploiting them. It is a process of recognition and spotting of new medical uses, outside the scope of the original pharmacological indication, for already approved/ existing drugs. Drug repurposing is a 3–12-year process with reduced safety and pharmacokinetic uncertainty. It is an excellent alternative over the de novo or traditional drug development process which is relatively a slower, time-consuming, costly, and a risk involved process.

Brief history on repurposing

History has observed numerous drug compounds that have been repurposed either opportunistic or accidental. Despite being far from new this strategy has attained appreciable momentum in the past few years; about one-third of the approvals in recent years count for drug repurposing, and at present around 25% of the annual revenue for

the pharmaceutical industries is generated by repurposed drugs. The most ancient example of drug repurposing could be acetylsalicylic acid. It was originally marketed as an analgesic but was repositioned in the 1980s and consequently, it evolved as an antiplatelet aggregation drug (at low doses only). This indication is still applying to prevent cardiovascular events.

Sildenafil is another megahit in the history of drug repurposing [2–7]. Sildenafil which is a phosphodiesterase type 5 (PDE5) inhibitor was brought to the market for the treatment of cardiovascular disorders like coronary artery disease (CAD), hypertension, and angina pectoris. It was realized during the trials that the patients taking sildenafil exhibited marked penile erection. In 1988, it was repurposed, and the outcome was that it was introduced in the market as an approved drug for erectile dysfunction.

Advantages of drug repurposing

Repurposing is preferred as a drug development strategy as it is efficient, economical, and riskless. The various advantages associated with repurposing are as follows:

- Repurposing simplifies the regulatory procedures for introducing a previously approved drug on the market.
- It considers previously known data, especially the drug's safety and toxicity, which makes the initial phases of development of a repurposed drug considerably faster and therefore cheaper.
- It increases the chances of introducing the drug in the market.

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➤ The drug does not undergo the initial stages of drug development as in the case of the traditional drug development process which takes up to nine years but instead goes directly to later phases i.e., the preclinical testing and clinical trials, thus reduces risk, time, and costs.

➤ There is a depletion of the risks associated with failures in the early stages of traditional drug development, this brings down the cost of the overall process.

➤ Due to known pharmacokinetics and pharmacodynamics (PK-PD) profile and other data (efficacy, safety, and toxicity) related to the already approved drugs, further processing becomes easier [8-10].

➤ It offers affordable, cheap, and faster treatment.

➤ It is a technique that requires fewer efforts when compared to the primitive drug development process.

Categories of drugs suitable for repurposing

➤ Drugs whose mode of action is like more than one disease.

➤ Drugs that fail to prove clinical efficacy (during the clinical trials) for a disease it was being processed for.

➤ Drugs that have been shelved for some reasons.

➤ Drugs for which the patents are going to expire.

➤ Drugs whose generic formulations have already been marketed.

➤ Drugs from academic institutions and public sector labs were never commercialized.

➤ Drugs that were discontinued for commercial or safety reasons.

➤ Drugs available in developing markets but not commercialized in the larger developed markets.

➤ Drugs with incremental new indications (also called line extension drugs).

➤ Drugs that are already in clinical development demonstrated polypharmacology.

Steps or stages

In drug repurposing, we opt for the identification and discovery of drug candidates for new uses, inspection of mechanism or signaling pathway involved in drug or disease and eventually proving the effectiveness of the drug in phase 2 and 3 clinical trials. Drug repurposing consists of four major steps,

➤ Selection of target compound

➤ Clinical trial (phase 2 and 3)

➤ NDA (New Drug Application)

➤ PMS (Post Marketing Surveillance)

Selection of target compound

Selection or identification of lead candidates is the most vital step of repurposing a drug. The selection of the target compound is based upon its pharmacological actions. Pharmacological actions apart from the principal or primary pharmacological action should be taken into consideration and the compound should be selected for repurposing. This step involves more advanced and systematic approaches required

for the generation of the latest hypothesis in drug repurposing [10-15]. Compounds with multi-mechanisms or acting on multiple receptors or other mediators or having multiple binding sites may be considered good targets for repurposing. This works well for repurposing drugs for few rare diseases or for ailments for which there is the least number of treatment options.

Clinical trial (phase 2 and 3): Once the target compound has been successfully selected, we proceed with the clinical trials of the same. Since the compounds selected for repurposing are already approved or existing ones, we do not necessarily need to go for the phase 1 trial as for the approved drugs the question of safety does not arise. For the phase 2 trial patient's groups with the target disease or for the condition for which the drug is to be repurposed are selected and the effectiveness of the compound in that condition is evaluated. Next, in the phase 3 trial larger patient population with the target disease is selected and the therapeutic benefits or any new indication other than the original pharmacological uses are confirmed.

NDA (new drug application): Next, through NDA (New Drug Application) the drug sponsors or people carrying out the research formally propose the FDA or DGCI for the re-approval of the drug considering the new indications for sale and marketing after successful phase 3 trial.

PMS (post marketing surveillance): This involves safety surveillance (Pharmacovigilance) after the drug receives permission to be sold in the market. The safety surveillance is intended to recognize any rare or long-term adverse effects over a bigger population and longer period, which was impractical during the phase 1-3 clinical trials. Harmful effects discovered in the PMS may result in the withdrawal of the drug from the market. In the case of a repurposed drug, its effectiveness or success considering the new indication is also assessed.

Conclusion

De novo drug development or the traditional system of drug development is time-consuming, high investment, and the risk-prone process has paved the way to look for an alternative strategy for drug development. Overcoming all these drawbacks, 'Drug repurposing' has drawn the attention of all the pharmaceutical industries and R&D sectors which offers faster and cheaper ways for bringing new drugs into the market. The repurposing of drugs for a therapeutic indication other than the one for which they were initially marketed is a growing trend. This approach presents lower R&D costs, higher success rates, lower investment risk, and reduces research time. Repurposing is a drug discovery method that could help treat patients and improve their quality of life by bringing new therapeutic options to market. However, this approach must be considered as an add-on rather than an alternative to the search for novel drugs.

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