INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

OPEN ACCESS

Review Article

Repurposing Existing Drugs for New Indications: A Modern Pharmacological Approach

Viraj Naravane*[1], Madhu Kalasad[2], Falguni Prabhu[3], Sonal Ghongade[4], Ram Hudekar[5], Srushti Pirankar[6]

[1]*College of Pharmacy (Poly), Sawarde.*
[2]*AGM College of pharmacy Varur hubballi.*
[3,6]*Swami Vivekanand Institute of Pharmaceutical Sciences, Hyderabad.*
[4]*Shree Prakashchand Jain College of Pharmacy and Research Palaskhede (Bk.) Jamner.*
[5]*Electronics Test and Development Centre (Government of India).*

ARTICLE INFO

Published: 3 Nov 2025
Keywords:
methodologies, advantages, challenges, and successful examples of drug repurposing
DOI:
10.5281/zenodo.17513561

ABSTRACT

Drug repurposing (also known as drug repositioning) has emerged as a promising strategy in modern pharmacology to identify new therapeutic uses for existing drugs. This approach offers significant advantages over traditional drug discovery, including reduced development costs, shorter timelines, and a higher probability of success. With advancements in computational biology, genomics, and artificial intelligence, drug repurposing has gained renewed momentum. This review highlights the concept, methodologies, advantages, challenges, and successful examples of drug repurposing, emphasizing its role in modern therapeutics and precision medicine.

INTRODUCTION

The process of discovering and developing new drugs is a complex, time-intensive, and financially demanding endeavor. It typically takes 10–15 years and costs approximately 1–2 billion USD to bring a new chemical entity (NCE) from the initial discovery phase to market approval. Despite these substantial investments, the success rate for new drug development remains low, with only a small fraction of compounds that enter clinical trials ultimately reaching approval. This inefficiency, coupled with the urgent need for new and effective therapies, especially for rare and emerging diseases, has prompted researchers and the pharmaceutical industry to explore alternative strategies for drug discovery. One such strategy that has gained significant momentum in recent years is drug repurposing, also known as drug repositioning or drug re-profiling. This modern

***Corresponding Author:** Viraj Naravane
Address: *College of Pharmacy (Poly), Sawarde.*
Email ✉: pratikshabpatil28@gmail.com
Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

pharmacological approach involves identifying new therapeutic uses for already approved, discontinued, shelved, or investigational drugs outside the scope of their original medical indication. Instead of starting from scratch, drug repurposing builds upon the pre-existing data of known drugs, including their pharmacokinetic, pharmacodynamic, toxicological, and clinical profiles. By leveraging this existing knowledge base, researchers can bypass several early phases of drug development, such as preclinical toxicology and safety assessment, which significantly reduces both time and cost. The global healthcare landscape has witnessed increasing instances where repurposed drugs have provided substantial clinical benefits. For example, the serendipitous discovery of sildenafil's efficacy in treating erectile dysfunction, while it was originally being tested for angina, revolutionized its use and opened a multi-billion-dollar therapeutic market. Similarly, thalidomide, once withdrawn due to teratogenic effects, found renewed life as an effective therapy for multiple myeloma and leprosy. These successes illustrate how existing drugs can be harnessed to address unmet medical needs with minimal risk and maximal efficiency. In the era of precision medicine, computational pharmacology, and artificial intelligence, drug repurposing has evolved from a trial-and-error approach to a data-driven scientific strategy. Advanced bioinformatics tools, molecular docking studies, network pharmacology, and systems biology models now enable researchers to identify new drug-target interactions more precisely. This integration of computational and experimental methods has expanded the horizons of drug repurposing, making it an essential component of modern drug discovery pipelines. Furthermore, global health emergencies such as the COVID-19 pandemic have highlighted the importance of drug repurposing. The urgent need for effective treatments led researchers to screen existing antiviral and immunomodulatory drugs for potential activity against SARS-CoV-2. Drugs such as remdesivir, dexamethasone, and tocilizumab were rapidly tested and deployed under emergency use authorizations, demonstrating how repurposing can accelerate therapeutic responses during crises. In summary, drug repurposing represents a paradigm shift in modern pharmacology, offering a pragmatic and efficient alternative to traditional drug discovery. It bridges the gap between innovation and accessibility, helping to deliver effective treatments to patients faster and at lower costs. As our understanding of disease mechanisms and drug actions continues to grow, repurposing will remain a powerful strategy in the development of next-generation therapeutics.

2. Concept of Drug Repurposing

Drug repurposing is defined as the process of discovering new therapeutic indications for existing drugs that have already been approved for other diseases or have reached advanced stages of clinical trials. Unlike traditional drug discovery, which involves the identification of a new target followed by the synthesis of novel molecules and extensive preclinical testing, repurposing capitalizes on compounds with well-characterized biological profiles. This approach is rooted in the understanding that many diseases share overlapping pathophysiological pathways, molecular mechanisms, or druggable targets, allowing a single compound to exhibit therapeutic potential across multiple conditions. The underlying scientific basis for drug repurposing lies in the pleiotropic nature of drugs — their ability to interact with multiple targets within the human body. Many drugs, originally developed for a specific receptor or enzyme, have been found to modulate additional pathways that play roles in

other diseases. For example, anti-inflammatory agents have demonstrated anticancer potential due to their effects on the tumor microenvironment, while certain antidiabetic drugs exhibit cardioprotective or neuroprotective actions.

There are generally two categories of repurposing:

1. On-target repurposing: The drug acts on the same biological target but in a different disease context.

Example: Aspirin, originally developed as an analgesic and antipyretic, was later found to inhibit platelet aggregation through the same COX inhibition pathway, making it valuable for preventing myocardial infarction and stroke.

2. Off-target repurposing: The drug acts on a new target unrelated to its original indication.

Example: Sildenafil, initially studied as a vasodilator for angina, was later found to inhibit phosphodiesterase type 5 (PDE5), leading to its successful use in treating erectile dysfunction and pulmonary arterial hypertension.

Historically, many repurposing discoveries were serendipitous, arising from unexpected clinical observations. However, modern pharmacology increasingly employs rational and systematic approaches based on data mining, molecular modeling, and genomic analysis. The availability of large-scale biological databases and computational tools enables researchers to predict new drug-disease relationships with unprecedented accuracy.

Notable examples include:

Thalidomide: Initially introduced as a sedative and withdrawn for teratogenicity, it was later found effective in multiple myeloma and erythema nodosum leprosum due to its anti-angiogenic and immunomodulatory properties.

Sildenafil: Developed for angina pectoris, it was repurposed for erectile dysfunction and pulmonary hypertension after its vasodilatory effects were found to enhance penile blood flow.

Aspirin: First marketed as a pain reliever, it became one of the most important drugs for cardiovascular prevention due to its antiplatelet activity.

Minoxidil: Originally designed as an antihypertensive, it was later repurposed for the treatment of alopecia due to its ability to stimulate hair follicles.

These examples underscore the potential of repurposing not only to revive older drugs but also to uncover novel therapeutic opportunities that can lead to significant clinical and commercial success.

In essence, the concept of drug repurposing bridges the gap between existing pharmacological knowledge and emerging therapeutic needs. With advancements in bioinformatics, network pharmacology, and systems biology, the process has become more strategic, targeted, and efficient. This shift from chance discovery to predictive science positions drug repurposing as a cornerstone of modern drug development, capable of addressing unmet medical challenges across diverse therapeutic areas.

Approaches to Drug Repurposing

Drug repurposing can be pursued through several complementary strategies. Depending on the available data, research objectives, and technological resources, repurposing can be achieved using experimental, computational (in silico), and clinical/real-world data-driven

approaches. Each method contributes uniquely to the identification of new therapeutic applications for existing drugs.

3.1 Experimental Approaches

Experimental or laboratory-based methods rely on direct testing of known drugs in biological systems to uncover new pharmacological activities. These approaches are fundamental to validating hypotheses and identifying novel indications that might not be predicted computationally. Major experimental techniques include:

a. Phenotypic Screening

Phenotypic screening involves assessing the observable biological effects of a drug on living cells, tissues, or model organisms without prior knowledge of its specific molecular target. By examining cellular morphology, viability, or biochemical markers, researchers can identify drugs that reverse disease-associated phenotypes.

Historically, phenotypic screening has played a crucial role in several major discoveries. For instance, the antipsychotic drug chlorpromazine and the anti-tuberculosis agent isoniazid were both identified through empirical screening. Today, advances in cell-based assays, organoid models, and high-content imaging have revitalized phenotypic screening as a key experimental approach in repurposing.

b. Target-Based Screening

Target-based repurposing focuses on known molecular targets—proteins, receptors, enzymes, or pathways—that are implicated in disease mechanisms. Existing drugs are tested for their ability to interact with these targets, thereby revealing new therapeutic uses. For example, inhibitors of specific kinases initially developed for oncology have shown potential in inflammatory and neurodegenerative diseases.

With the advent of structural biology and proteomics, researchers can map the interaction profiles of drugs across multiple biological targets, leading to the identification of previously unrecognized pharmacological effects.

c. High-Throughput Screening (HTS)

High-throughput screening is a technology-driven approach that enables the rapid testing of thousands of compounds against biological assays or disease models. Automation, robotics, and miniaturized assay systems allow researchers to evaluate the pharmacological activity of large chemical libraries efficiently. HTS is particularly useful for repurposing because it can systematically screen collections of FDA-approved drugs (e.g., the Prestwick Chemical Library or the NIH Clinical Collection) against novel disease models. The success of remdesivir during the COVID-19 pandemic was facilitated by such high-throughput repurposing screens that rapidly identified its antiviral potential.

3.2 Computational (In Silico) Approaches

With the explosion of biological and pharmacological data, computational approaches—also known as in silico methods—have become powerful tools for drug repurposing. These rely on bioinformatics, systems biology, and artificial intelligence (AI) to predict new drug-disease relationships based on existing molecular, clinical, and chemical information.

a. Molecular Docking and Network Pharmacology

Molecular docking involves simulating the interaction between a drug molecule and potential biological targets to estimate binding affinity and

stability. This approach helps identify new protein targets that may be modulated by an existing drug.

Network pharmacology, on the other hand, visualizes the complex relationships between drugs, targets, and diseases in interconnected biological networks. By integrating multi-omics data (genomics, proteomics, and metabolomics), network analysis can reveal shared pathways among diseases and predict repurposing candidates with multi-target effects.

b. Transcriptomic and Proteomic Data Analysis

Drugs often induce changes in gene and protein expression patterns. Comparing these transcriptomic signatures (drug-induced expression profiles) with disease-associated gene expression data can identify compounds that may reverse disease states. For example, the Connectivity Map (CMap) database enables researchers to match drug-induced gene expression changes with disease signatures to predict new indications.

c. Machine Learning and Artificial Intelligence (AI)

AI-driven algorithms can analyze massive datasets to uncover non-obvious associations between drugs and diseases. Machine learning models use chemical structures, side-effect profiles, target affinities, and clinical data to predict repurposing opportunities. Deep learning techniques have shown particular promise in predicting drug-target interactions, drug synergy, and polypharmacology.

For instance, AI models helped identify baricitinib, a Janus kinase inhibitor, as a potential treatment for COVID-19 due to its predicted interaction with viral entry pathways.

d. Drug–Target Interaction Databases

Several curated databases facilitate computational drug repurposing:

DrugBank: Combines detailed drug, target, and mechanism data.

ChEMBL: Provides bioactivity information for small molecules.

PubChem: Contains experimental bioassay results.

RepurposeDB and CLUE (Connectivity Map): Specifically designed for repositioning studies.

Such databases empower researchers to perform virtual screening and integrate chemical, biological, and clinical information efficiently.

Computational repurposing dramatically reduces costs and time while generating data-driven hypotheses that can later be validated experimentally.

3.3 Clinical and Real-World Data Approaches

Clinical and real-world data-driven strategies leverage the enormous wealth of information derived from clinical trials, electronic health records (EHRs), insurance claims, and post-marketing surveillance systems. These data sources can reveal unexpected therapeutic benefits or side effects that hint at new drug indications.

For example:

Retrospective analysis of patient records showed that metformin, an antidiabetic drug, is associated with reduced cancer incidence, leading to its investigation as an anticancer agent.

Statins, widely prescribed for hypercholesterolemia, were found to possess anti-

inflammatory and immunomodulatory effects based on real-world data.

Moreover, adverse event databases such as the FDA's Adverse Event Reporting System (FAERS) can uncover off-target activities that may be therapeutically useful.

By integrating EHR-based analytics with AI algorithms, researchers can systematically mine population-level data to discover new drug–disease correlations.

Clinical and real-world data approaches thus complement experimental and computational strategies, bridging the gap between laboratory discovery and clinical applicability.

4. Advantages of Drug Repurposing

Drug repurposing offers multiple advantages compared to conventional drug development. Its benefits are summarized below:

Aspect	Benefit
Time Efficiency	Significantly reduces the time required to bring a therapy to market, since preclinical and early clinical testing are often already completed.
Cost Reduction	Lowers research and development costs because safety profiles, pharmacokinetics, and manufacturing processes are already established.
Higher Success Rate	Increases the likelihood of clinical and regulatory success due to existing data on safety and efficacy.
Faster Patient Access	Enables quicker delivery of effective treatments to patients, particularly for unmet medical needs or rare diseases.
Known Safety Profile	Reduces the risk of unexpected adverse effects since the drug has already undergone human testing.
Versatility	Allows exploration of new therapeutic indications across different diseases, including emerging or rare conditions.
Support During Emergencies	Provides rapid-response options in public health crises (e.g., COVID-19) by repurposing existing drugs.

Beyond these tangible benefits, repurposing contributes to global healthcare equity by offering affordable therapies and revitalizing older drugs that might otherwise be abandoned. It also helps in addressing orphan and neglected diseases, for which conventional drug discovery is often economically unviable.

5. Challenges and Limitations

Despite its promise, drug repurposing faces several scientific, legal, and commercial obstacles:

a. Intellectual Property (IP) Issues

Securing new patents for already known compounds can be challenging. Since the original patents may have expired, innovators face difficulties in obtaining market exclusivity for the new indication, limiting commercial incentive.

b. Regulatory Challenges

Regulatory frameworks for repurposed drugs are not uniformly established worldwide. Authorities such as the U.S. FDA and EMA require robust clinical evidence for new indications, even for approved drugs, which can prolong timelines and increase costs.

c. Mechanistic Uncertainty

In some cases, the exact mechanism of action in the new disease context may remain unclear, leading to concerns about efficacy and safety in broader populations.

d. Market and Financial Barriers

Pharmaceutical companies may lack motivation to invest in repurposing due to lower financial returns compared to novel drug patents. Additionally, smaller academic or public sector entities often lack resources to conduct confirmatory clinical trials.

e. Data Integration and Quality

Inconsistent data quality, lack of standardization among databases, and incomplete information on off-target effects can limit computational predictions and hinder validation efforts.

Addressing these challenges requires coordinated efforts among academia, industry, and regulatory authorities, along with supportive policies for intellectual property protection and data transparency.

6. Successful Examples of Drug Repurposing

Drug repurposing has led to several landmark successes that have transformed clinical practice and pharmaceutical markets. Some notable examples include:

Drug	Original Indication	Repurposed Indication	Impact/Significance
Sildenafil (Viagra®)	Developed for angina and hypertension	Repurposed for erectile dysfunction; later also approved for pulmonary arterial hypertension	Generated one of the most successful commercial drugs globally and improved quality of life for millions.
Thalidomide	Initially used as a sedative and for morning sickness	Repurposed for multiple myeloma and erythema nodosum leprosum	Revived a withdrawn drug and became a cornerstone in cancer therapy with strict regulatory control.
Minoxidil (Rogaine®)	Developed as an antihypertensive	Repurposed for androgenic alopecia (hair loss)	Created a major dermatologic product with wide consumer use.
Methotrexate	Initially an anti-cancer chemotherapeutic	Repurposed for autoimmune diseases such as rheumatoid arthritis and psoriasis	Provided a low-cost, effective treatment for chronic inflammatory diseases.
Azidothymidine (AZT)	Originally designed for cancer therapy	Repurposed as the first approved antiretroviral drug for HIV/AIDS	Marked a turning point in HIV treatment and public health response.
Bupropion (Wellbutrin® / Zyban®)	Developed as an antidepressant	Repurposed for smoking cessation	Expanded its therapeutic reach and public health impact.
Finasteride (Proscar® / Propecia®)	Developed for benign prostatic hyperplasia (BPH)	Repurposed for male pattern baldness	Achieved significant commercial success and broadened its market.

These examples demonstrate that repurposed drugs can significantly broaden therapeutic horizons and generate immense social and commercial value. For instance, thalidomide, once considered a catastrophic failure, now serves as a life-extending therapy for cancer patients. Sildenafil, initially a failed cardiovascular drug, became one of the most commercially successful treatments in modern medicine.

7. Role of Artificial Intelligence and Bioinformatics

The integration of Artificial Intelligence (AI), bioinformatics, and big data analytics has transformed the landscape of modern drug discovery and repurposing. Traditional methods of identifying new therapeutic uses for existing drugs relied heavily on serendipity or time-consuming experimental testing. However, with the explosion of biomedical data and advances in computational power, AI-based approaches now enable researchers to explore vast chemical, genomic, and clinical datasets to discover new drug–disease relationships with remarkable efficiency.

7.1 Artificial Intelligence in Drug Repurposing

AI, particularly machine learning (ML) and deep learning (DL), has proven instrumental in analyzing complex biological data and predicting drug efficacy across multiple diseases. ML algorithms can process large volumes of structured and unstructured data, including chemical structures, pharmacokinetic parameters, side-effect profiles, and clinical outcomes, to identify hidden patterns and correlations.

Through supervised and unsupervised learning techniques, AI systems can:

- Predict drug–target interactions and binding affinities.
- Identify new therapeutic indications by mapping molecular similarities among drugs and diseases.
- Recognize off-target effects that could be beneficial for other disorders.
- Rank and prioritize repurposing candidates for further experimental validation.

For instance, natural language processing (NLP) tools can mine scientific literature and clinical trial repositories to extract relationships between drugs, targets, and diseases. AI platforms such as IBM Watson for Drug Discovery and Insilico Medicine have successfully applied these technologies to identify novel repurposing opportunities within oncology and neurology.

7.2 Network Pharmacology and Systems Biology

Network pharmacology is another cornerstone of AI-driven repurposing. It maps the intricate interactions among drugs, targets, pathways, and diseases, visualizing them as interconnected biological networks. This systems-level approach acknowledges that most drugs act on multiple targets (polypharmacology), and many diseases result from complex molecular interactions rather than single gene defects.

By integrating these networks, researchers can uncover drugs that influence multiple disease-related pathways simultaneously — a valuable feature for conditions like cancer, metabolic disorders, and neurodegenerative diseases.

7.3 Bioinformatics and Omics Integration

Bioinformatics plays a vital role in managing and interpreting massive biological datasets derived from genomics, transcriptomics, proteomics, and metabolomics ("multi-omics" data). Combining omics data enables a systems biology approach, where the collective behavior of genes, proteins, and metabolites is analyzed to identify disease signatures and drug responses.

By comparing disease-associated gene expression profiles with drug-induced transcriptomic signatures (as in the Connectivity Map, CMap), researchers can identify compounds that reverse pathological gene expression patterns. Similarly, integrating proteomic and metabolomic data

allows scientists to understand drug effects at the molecular and cellular level.

7.4 Advantages of AI-Driven Repurposing

AI and bioinformatics offer several advantages in the repurposing process:

- Speed: Rapidly screens thousands of compounds virtually before experimental validation.
- Cost-efficiency: Minimizes the need for extensive laboratory testing.
- Precision: Predicts the most promising drug candidates for specific molecular subtypes of diseases.
- Personalization: Facilitates precision medicine by aligning drug responses with patient-specific genetic profiles.

8. Drug Repurposing During the COVID-19 Pandemic

The outbreak of the COVID-19 pandemic in late 2019 created an unprecedented global health emergency. With millions of infections and deaths worldwide, there was an urgent need to develop effective treatments within an extremely short timeframe. Traditional drug discovery was impractical due to the time constraints; thus, drug repurposing became a primary strategy to identify potential therapeutics against SARS-CoV-2.

8.1 Rapid Screening of Existing Drugs

Researchers immediately began screening existing antiviral, anti-inflammatory, and immunomodulatory drugs to identify compounds with activity against the novel coronavirus. High-throughput computational methods, molecular docking studies, and AI-based analyses were used to evaluate thousands of drugs for their potential to inhibit viral entry, replication, or the host immune response.

8.2 Notable Repurposed Drugs

Remdesivir: Originally developed for Ebola virus infection, remdesivir showed efficacy in inhibiting the RNA-dependent RNA polymerase of SARS-CoV-2. It became the first antiviral to receive emergency use authorization (EUA) for COVID-19 treatment by the U.S. FDA.

Dexamethasone: A long-established corticosteroid, dexamethasone was found to significantly reduce mortality in severely ill COVID-19 patients requiring oxygen or mechanical ventilation. Its anti-inflammatory effects helped mitigate the cytokine storm associated with severe infection.

Tocilizumab: An IL-6 receptor antagonist used in rheumatoid arthritis, tocilizumab proved effective in managing hyperinflammatory responses and reducing disease severity in hospitalized patients. Other drugs such as hydroxychloroquine, favipiravir, and lopinavir/ritonavir were also investigated, though not all demonstrated clinical efficacy. The pandemic showcased the speed and adaptability of repurposing as a global scientific effort.

8.3 Lessons from the Pandemic

The COVID-19 experience underscored several key lessons:

Drug repurposing can provide rapid therapeutic options during emerging infectious outbreaks.

Collaboration among academic institutions, pharmaceutical companies, and regulatory agencies can expedite clinical trials. The integration of AI-driven prediction, real-world clinical data, and molecular modeling can guide

large-scale screening efficiently. Thus, COVID-19 served as a global demonstration of how repurposing can save time, resources, and lives during public health crises.

9. Future Perspectives

The future of drug repurposing is poised for remarkable expansion through the integration of computational prediction models, real-world evidence, and precision medicine. As biological databases, AI algorithms, and genomic technologies continue to evolve, repurposing will become even more targeted, efficient, and patient-specific.

9.1 Integration of Computational and Clinical Data

Combining computational models with real-world clinical data will enable a more accurate understanding of drug efficacy across diverse populations. This fusion allows researchers to predict not only new indications but also optimal patient groups, dosing regimens, and combination therapies.

9.2 Collaborative Ecosystems

Successful repurposing requires close collaboration between academia, industry, government agencies, and healthcare organizations. Collaborative initiatives like the Open Targets Platform and NIH NCATS (National Center for Advancing Translational Sciences) have established frameworks for data sharing and validation, facilitating faster translation of research into clinical practice.

9.3 Regulatory and Intellectual Property Reforms

To fully harness the potential of repurposing, regulatory pathways must evolve to accommodate repurposed drugs more efficiently. Agencies such as the FDA and EMA are developing dedicated guidelines to streamline approval for new indications. Additionally, establishing clear intellectual property (IP) frameworks—including data exclusivity and secondary patents—can incentivize pharmaceutical companies to invest in repurposing projects.

9.4 Advancing Precision and Personalized Medicine

As medicine moves toward personalization, drug repurposing will play a critical role in matching existing therapeutics to patient-specific genetic or molecular profiles. AI-based models can predict which subsets of patients are most likely to respond to a given repurposed therapy, reducing trial-and-error in treatment selection.

9.5 Global Databases and Open Science

Developing open-access databases and global data-sharing initiatives will enhance transparency and accelerate innovation. By integrating chemical, biological, and clinical information into unified platforms, researchers worldwide can collectively identify promising candidates for emerging and rare diseases. In the coming years, drug repurposing will likely evolve into a central pillar of translational pharmacology, complementing traditional drug discovery to provide faster, safer, and more cost-effective therapeutic solutions.

10. CONCLUSION

Drug repurposing has emerged as a transformative paradigm in modern pharmacology, bridging the gap between innovation and accessibility. By harnessing the potential of existing drugs, it enables the rapid identification of new therapeutic applications while minimizing time, cost, and risk.

The integration of artificial intelligence, bioinformatics, and systems biology has revolutionized repurposing, making it more predictive and precise than ever before. As demonstrated during the COVID-19 pandemic, this approach can provide timely solutions to urgent health challenges and accelerate responses during global crises. Despite challenges such as intellectual property limitations and regulatory barriers, the growing collaboration among academic, industrial, and governmental stakeholders offers hope for a more coordinated and efficient repurposing ecosystem. Ultimately, drug repurposing embodies the essence of translational research—transforming existing scientific knowledge into practical therapeutic advances. It not only extends the life cycle of known drugs but also offers new hope for treating rare, neglected, and emerging diseases, contributing significantly to global health and patient welfare.

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HOW TO CITE: Viraj Naravane, Madhu Kalasad, Falguni Prabhu, Sonal Ghongade, Ram Hudekar, Srushti Pirankar, Repurposing Existing Drugs for New Indications: A Modern Pharmacological Approach, Int. J. of Pharm. Sci., 2025, Vol 3, Issue 11, 320-330 https://doi.org/10.5281/zenodo.17513561