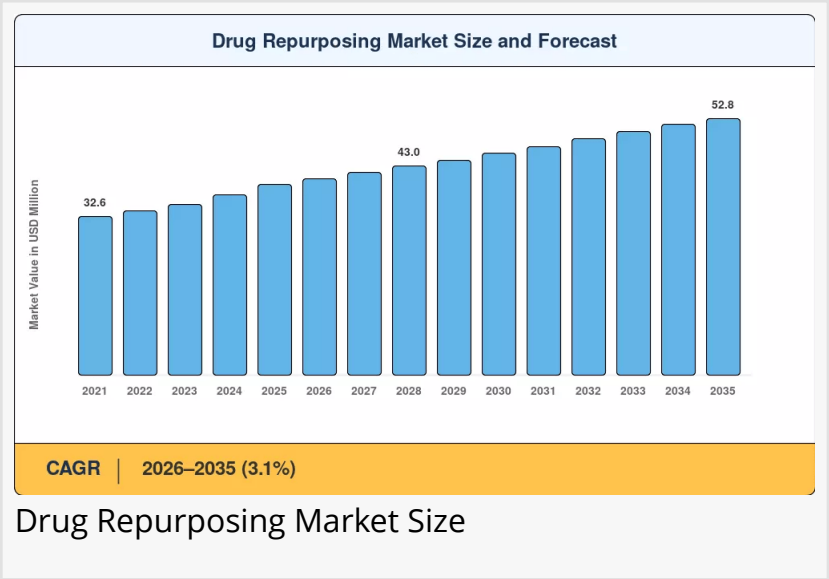
Drug Repurposing Market to reach USD 52.80 Billion by 2035 at 3.1% CAGR

Drug Repurposing Market to Surge from USD 40.40 Bn in 2026 to USD 52.80 Bn by 2035-Powered by Patent-Cliff Revenue Pressure, AI-Driven Drug Repositioning



Drug Repurposing Market Size

NY, CA, UNITED STATES, June 10, 2026 /EINPresswire.com/ -- As per Market Research Future, the global Drug Repurposing Market size to reach USD 52.80 Billion by 2035 from USD 40.40 Billion in 2026, at a CAGR of 3.1% during the forecast period 2026--2035. The market base was estimated at USD 39.20 Billion in 2025. The 3.1% CAGR---reflecting a fundamental shift in pharmaceutical R&D strategy rather than cyclical demand---is driven by three converging structural forces: patent cliffs threatening an estimated USD 197 Billion in branded-drug revenue by 2031, forcing innovators to accelerate therapeutic reprofiling strategies for existing drug new indication candidates rather than costly de novo discovery; regulatory pathways such as the FDA's 505(b)(2) route and the EMA's hybrid application procedure formalizing frameworks that reward therapeutic reprofiling with shortened approval timelines; and the emergence of AI-native computational drug repositioning platforms capable of compressing candidate identification from 3--5 years to under 12 months and cutting preclinical costs by an estimated 40--60%.

National governments and research institutions are amplifying this momentum. The National Institutes of Health's NCATS program has committed over USD 750 Million in cumulative funding toward translational science initiatives that directly support off-label drug repositioning programs. The FDA's Real-World Evidence Program, formalized under the 21st Century Cures Act, now permits real-world data from electronic health records and claims databases to support supplemental new drug applications for FDA-approved drug repurposing.

The ICH is working toward global alignment on data-sharing standards for repurposed drugs, which could reduce duplicative regulatory submissions by up to 50% by 2035. Together, these initiatives are creating the regulatory infrastructure and funding ecosystems on which

computational drug repositioning depends.

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Key Market Trends & Growth Drivers

Patent-Cliff Revenue Pressure and Lifecycle Extension Strategy

An estimated USD 197 Billion in branded-drug revenue faces generic erosion by 2031, according to EvaluatePharma data. This unprecedented wave of patent expirations is forcing pharmaceutical companies to pursue a therapeutic reprofiling strategy as a lifecycle-extension mechanism. Companies like Pfizer and Novartis have established dedicated repurposing units that screen existing drug new indication opportunities across their portfolios, targeting the 505(b)(2) pathway to recapture revenue streams before generics fully commoditize their blockbusters.

The 505(b)(2) route lets sponsors reference published safety and efficacy data from prior approvals, eliminating the need for full preclinical programs. This typically cuts development costs by 40--60% and shortens timelines by 2--4 years compared to a standard NDA. Early-adopter pharmaceutical manufacturers report that therapeutic reprofiling strategies can extend blockbuster revenue tails by 5--8 years when integrated into portfolio lifecycle management, making this the single largest structural driver of the Drug Repurposing Market through 2035.

AI-Driven Computational Drug Repositioning Platforms

Machine-learning platforms are compressing candidate identification from 3--5 years to under 12 months for the Drug Repurposing Market. Recursion Pharmaceuticals' AI platform has screened over 40 Billion biological relationships, while BenevolentAI's knowledge graph identified baricitinib for COVID-19 treatment in under 48 hours. The convergence of multi-omics data, network pharmacology, and natural-language processing on biomedical literature is enabling computational drug repositioning at a scale that was unthinkable five years ago, with an estimated USD 2.4 Billion invested in AI-drug-discovery startups in 2024 alone.

Network pharmacology and transcriptomic signature matching currently achieve Phase II success rates of 18--24%, roughly double the rate for traditional phenotypic screening. Multi-omics integration is expected to push success rates above 30% by 2030. By 2030, an estimated 60% of Drug Repurposing Market candidates will originate from AI-driven platforms that integrate genomic, proteomic, and clinical data. Computational drug repositioning will evolve from single-target screening to multi-modal network analysis, enabling simultaneous evaluation of thousands of compound-indication pairs.

Orphan-Drug Incentive Frameworks and Rare-Disease Repurposing

The US Orphan Drug Act provides seven years of market exclusivity, 25% tax credits on clinical trial costs, and FDA fee waivers---a combination that makes existing drug new indication development for rare diseases financially attractive despite small patient populations. Europe's parallel incentive structure offers ten years of market exclusivity under Regulation (EC) 141/2000. Japan's SAKIGAKE designation system fast-tracks orphan-disease repurposing candidates. These policies collectively channel investment toward a therapeutic reprofiling strategy for diseases that would otherwise lack commercial viability.

There are greater than 7,000 uncommon diseases and less than 5% have therapy options. Systematic pairing of molecular targets across rare-disease pathways is possible with computational drug repositioning, while orphan-drug incentives de-risk the investment. Approximately 85 FDA-approved drug repurposing candidates are in active orphan-indication trials as of 2025. In November 2024, the FDA issued updated draft guidance on the use of real-world evidence for 505(b)(2) submissions, strengthening pathways for FDA-approved drug repurposing programs and further de-risking rare-disease development.

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Market Segment Insights

BY THERAPEUTIC AREA

Oncology: Dominant segment with 40.1% revenue share in 2024. Reflecting sustained pipeline investment in immuno-oncology combinations and off-label drug repositioning for treatment-resistant tumors. Computational drug repositioning has identified over 340 non-oncology compounds with anti-tumor activity currently in clinical evaluation.

Rare & Orphan Diseases: Fastest-growing therapeutic area at 15.9% CAGR (2026--2035). Supported by orphan-drug incentive programs and venture funding surges. Dedicated rare-disease repurposing platforms offer premium pricing and long exclusivity opportunities.

CNS Disorders: Third-largest therapeutic area, with USD 6.8 Billion in 2025. Computational drug repositioning accelerating candidate identification for Alzheimer's and Parkinson's neurodegenerative conditions.

Infectious Diseases: USD 4.1 Billion in 2025, fueled by antimicrobial resistance concerns. Existing antivirals and antifungals are being systematically screened for activity against resistant bacterial strains using high-throughput assays, with three repurposed candidates currently in Phase III for MDR tuberculosis.

Cardiovascular: ~8.3% of 2024 revenue; off-patent statin and antihypertensive repurposing into heart failure and metabolic indications. Other Therapeutic Areas: Autoimmune and metabolic indications growing at 5.7% CAGR, reflecting expanding computational drug repositioning

beyond oncology and rare disease.

BY MOLECULE TYPE

Small-Molecule Drugs: Dominant segment with 69.4% market share in 2024. Benefiting from well-characterized safety profiles, lower reformulation costs, and extensive existing drug new indication safety databases that enable faster regulatory submissions through 505(b)(2) and similar abbreviated pathways.

Peptides & Biologics: Fastest-growing molecule type at 14.1% CAGR (2026--2035). As therapeutic reprofiling strategy extends to complex molecules with declining manufacturing costs, computational drug repositioning is expanding to protein-protein interaction networks and biosimilar manufacturing capacity is freeing up production for repurposed biologic formulations.

Nucleic Acids & Cell Therapies: Emerging segment at USD 1.2 Billion in 2025, representing next-generation therapeutic reprofiling strategy for advanced modalities.

BY END USER

Pharmaceutical & Biotechnology Companies: Largest segment at ~59.1% revenue share in 2024. Investing in internal pipeline lifecycle extension, dedicated repurposing units, and off-label drug repositioning to offset patent-cliff losses and extend blockbuster product lifecycles.

Contract Research Organizations: Fastest-growing end user at 13.4% CAGR (2026--2035). Driven by demand for outsourced computational drug repositioning expertise and regulatory filing support for existing drug new indication programs. CROs are increasingly offering Drug-Repositioning-as-a-Service on subscription platforms.

Academic & Research Institutes: USD 4.6 Billion in 2025, supported by government translational funding including NIH NCATS' cumulative USD 750 Million commitment. Others: Nonprofit and philanthropic drug access programs at ~4.8% of 2024 revenue, expanding access to repurposed therapies in low- and middle-income countries.

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Regional Outlook

North America --- Dominant Market (~48.7% Share, 2024)

The United States generates approximately 82.3% of North American Drug Repurposing Market revenue, driven by robust FDA-approved drug repurposing pathways and deep venture capital

ecosystems. The 505(b)(2) pathway processed a record 187 applications in 2024, reflecting growing industry confidence in FDA-approved drug repurposing routes. The NIH's NCATS program has disbursed over USD 750 Million cumulatively toward translational science programs that specifically support therapeutic reprofiling strategy.

Canada contributes through CIHR translational grants and provincial innovation funds supporting off-label drug repositioning research at major academic medical centers. Mexico is growing at 5.4% CAGR on COFEPRIS regulatory modernization. North America's dominance rests on the maturity of its 505(b)(2) framework, the depth of its AI-drug-discovery startup ecosystem, and the scale of its real-world evidence infrastructure.

Europe --- Second Largest (~24.3% Share, 2024)

Europe's Drug Repurposing Market benefits from the EMA's centralized procedure and adaptive-licensing framework, which allows conditional marketing authorizations based on smaller datasets for existing drug new indication submissions. Germany leads regionally with 27.4% of European revenue, anchored by BfArM regulatory excellence and the highest volume of repurposing-related variations in the EU. The UK contributes 22.1% of regional revenue through the MHRA's Innovative Licensing and Access Pathway, which has emerged as a leader in computational drug repositioning facilitation.

France is advancing through ANSM adaptive repurposing protocols and its national genomics initiative. Italy is growing at 8.3% CAGR on AIFA compassionate use programs. Spain contributes through ISCIII translational research grants. The Nordic countries are growing at 9.1% CAGR on EHR-integrated repositioning analytics. Russia holds ~4.2% of regional share through domestic pharmaceutical self-sufficiency initiatives. The rest of Europe is growing at 3.6% CAGR on EU Horizon Europe funding.

Asia-Pacific --- Fastest-Growing Region (12.5% CAGR, 2026--2035)

Asia-Pacific is the highest-growth corridor in the Drug Repurposing Market. China holds 34.6% of regional revenue, with the NMPA introducing expedited review pathways for repurposed molecules in 2023, cutting approval timelines by up to 40%. India is growing at 13.7% CAGR on the back of CDSCO fast-track mechanisms and 50--65% cost savings on clinical trials compared to Western benchmarks, making it a hub for therapeutic reprofiling strategy validation studies.

Japan contributes 22.8% of regional revenue through PMDA SAKIGAKE designation for orphan-disease repurposing. South Korea is growing at 11.9% CAGR on MFDS biotech incentives. ASEAN is growing at 9.4% CAGR on regional harmonization through the ASEAN Mutual Recognition Agreement. The rest of Asia-Pacific is growing at 7.8% CAGR on clinical infrastructure build-out. The region's rapid expansion is gradually redistributing global market weight toward the east.

Middle East & Africa --- Emerging Opportunity (7.2% CAGR, 2026--2035)

Saudi Arabia's Vision 2030 initiative anchors the region with 31.5% of regional revenue, targeting local pharmaceutical manufacturing capacity and therapeutic reprofiling strategy partnerships with global CROs. The UAE is growing at 8.9% CAGR on MOHAP innovation licensing. South Africa contributes 24.7% of regional revenue through MRC translational research programs focused on HIV-TB co-infection and neglected tropical diseases, where existing drugs' new indication approaches offer the most cost-effective route to expanded treatment access.

Egypt is growing at 7.4% CAGR on EDA regulatory reform. The rest of MEA is growing at 5.8% CAGR on WHO prequalification pathways. The region's focus skews toward infectious-disease repurposing, particularly for diseases where computational drug repositioning on existing antiparasitic and antiviral libraries offers the fastest path to treatment access.

Competitive Landscape and Recent Developments

The Drug Repurposing Market exhibits medium concentration, with the top five players collectively accounting for an estimated 28--35% of global revenue. The Herfindahl-Hirschman Index sits below 1,200, reflecting a fragmented landscape where large pharma incumbents compete with specialized AI-driven biotechnology firms and CROs offering therapeutic reprofiling strategy services. Competition is intensifying around proprietary data lakes, federated learning architectures, and integrated Drug-Repositioning-as-a-Service platforms.

The competitive landscape is stratified between large pharmaceutical companies with dedicated repurposing units controlling end-to-end lifecycle extension workflows, AI-native disruptors reshaping discovery economics through computational drug repositioning, and CROs offering subscription-based therapeutic reprofiling strategy services to mid-size pharma companies that lack internal AI capabilities.

KEY COMPANIES AND RECENT MILESTONES

Novartis AG (January 2025): Established a dedicated Drug Repurposing Center of Excellence in Basel, committing USD 350 Million over five years to systematic therapeutic reprofiling strategy across its off-patent portfolio. Estimated revenue share: ~6--9% of global Drug Repurposing Market.

Pfizer Inc. (2024--2025): Maintains a broad pipeline of repurposed candidates through its internal repurposing unit, leveraging post-patent monetization strategy to offset blockbuster revenue erosion. Estimated revenue share: ~5--8%.

Recursion Pharmaceuticals (March 2025): Expanded its AI platform to screen over 40 Billion biological relationships, announcing three new oncology candidates identified through computational drug repositioning. Estimated revenue share: ~3--5%.

BenevolentAI (2024--2025): Knowledge-graph-based target identification platform identified baricitinib for COVID-19 treatment in under 48 hours, demonstrating the speed advantage of NLP-driven off-label drug repositioning. Estimated revenue share: ~2--4%.

Teva Pharmaceutical (June 2024): Partnered with a South Korean CRO to advance existing drug new indication studies for three CNS compounds in Asia-Pacific markets, capitalizing on cost-competitive trial infrastructure. Estimated revenue share: ~4--6%.

AbbVie Inc. (2024--2025): Investing in immunology and oncology repurposing for its autoimmune portfolio, applying therapeutic reprofiling strategy to extend the lifecycle of key assets. Estimated revenue share: ~3--5%.

Future Outlook: 2026--2035

By 2030, an estimated 60% of Drug Repurposing Market candidates will originate from AI-driven platforms that integrate genomic, proteomic, and clinical data. Computational drug repositioning will evolve from single-target screening to multi-modal network analysis, enabling simultaneous evaluation of thousands of compound-indication pairs. Companies investing early in proprietary data lakes and federated learning architectures will establish durable competitive moats.

The ICH is working toward global alignment on data-sharing standards for repurposed drugs, which could reduce duplicative regulatory submissions by up to 50% by 2035. FDA-EMA mutual-recognition agreements for specific FDA-approved drug repurposing categories are under discussion, and APEC's regulatory convergence initiatives will benefit the Drug Repurposing Market in Asia-Pacific by enabling simultaneous multi-market submissions. Regulatory convergence will compress global launch timelines from the current 12--24 month lag in emerging markets toward near-simultaneous worldwide availability.

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