

Oncology Biosimilars Market to Hit USD 24 Billion by 2035 | Sandoz, Pfizer, Celltrion Lead – Fact.MR

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The [Oncology Biosimilars Market](#) is estimated to be worth USD 10.9 billion in 2025, according to Fact.MR's report states that the valuation will expand at an 8.1% CAGR during the forecast period and account for USD 24 billion by 2035. This robust growth is driven by the escalating global cancer burden, patent expirations of blockbuster biologics, and the urgent need for cost-effective cancer treatments. The

market is benefiting from increasing regulatory approvals, clinician acceptance, and investments in biosimilar manufacturing, particularly in regions with high cancer incidence like North America, Europe, and Asia-Pacific. The United States, a key market, is expected to grow at a CAGR of 9.5% through 2035, reflecting strong reimbursement policies and R&D efforts.



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Oncology Biosimilars Market Technology Development:

Technological advancements are transforming the oncology biosimilars landscape, emphasizing scalability, safety, and efficiency. High-tech manufacturing technologies, including single-use bioreactors and continuous processing, have improved production consistency and reduced costs, enabling biosimilars to match reference biologics in quality. AI-enabled process optimization is adopted by 66% of companies, streamlining development and minimizing variability in comparative clinical trials. Digital pharmacovigilance tools, used by 60% of stakeholders, facilitate real-time monitoring of safety and efficacy, building clinician trust. Innovations like advanced analytics for immunogenicity assessments and biosimilar interchangeability studies are accelerating regulatory approvals. In regions like Asia-Pacific,

localized production with enhanced cold-chain logistics addresses supply challenges.

Oncology Biosimilars Market Demand and Impact Analysis:

Demand for oncology biosimilars is surging due to the rising global cancer incidence, with over 20 million new cases annually, and the high cost of originator biologics, often exceeding \$100,000 per treatment course. Biosimilars offer 20-30% cost savings, enhancing access for patients and alleviating healthcare system burdens. Patent expirations of drugs like trastuzumab, bevacizumab, and rituximab have opened floodgates for biosimilar entry, driving competition and price reductions. Regulatory harmonization and favorable policies in Europe and North America promote substitution, while Asia-Pacific's growing generic industry fuels uptake. However, challenges like clinician hesitancy—addressed by 83% of stakeholders emphasizing transparent data—and supply chain issues, noted by 73% as a barrier, could hinder growth. The shift toward personalized medicine increases demand for targeted biosimilars, impacting disease indications like blood cancer.

Oncology Biosimilars Market Analysis by Top Investment Segments:

The oncology biosimilars market is segmented by drug class (G-CSF, monoclonal antibodies, hematopoietic agents), disease indication (breast cancer, non-small cell lung cancer, blood cancer, colorectal cancer, neutropenia, others), distribution channel (hospital pharmacy, online pharmacy, retail pharmacy), and region. Monoclonal antibodies dominate with a 40% share in 2025, driven by high demand for treatments like trastuzumab biosimilars for breast cancer, making it a prime investment area due to patent expirations and scalability. Hematopoietic agents hold 35%, lucrative for managing chemotherapy side effects, with products like filgrastim biosimilars offering strong returns in emerging markets.

Oncology Biosimilars Market Across Top Countries

1. The United States, projected at a 9.5% CAGR, benefits from FDA incentives, high cancer rates, and collaborations, with a focus on cost-cutting via reimbursement.
2. The UK, at 8.8% CAGR, leverages NHS promotion and aging population demands, emphasizing educational campaigns for adoption.
3. France grows at 8.2% CAGR, driven by substitution policies and elderly cancer incidence, with public procurement enhancing availability.
4. Germany, at 8.5% CAGR, excels with robust reimbursement and inpatient/outpatient incentives, supporting steady biosimilar penetration.

Leading Oncology Biosimilars Companies and Their Industry Share:

The oncology biosimilars market is competitive, with multinational leaders dominating through innovation and global reach. Key players include Sandoz International GmbH (18-22% share), Pfizer, Inc. (14-18%), Celltrion Inc. (12-15%), Dr. Reddy's Laboratories Ltd. (10-13%), and Biocon (9-

12%), collectively holding over 60% of the market. Sandoz leads with its early-mover advantage in rituximab and filgrastim biosimilars, backed by Novartis' infrastructure. Pfizer excels in monoclonal antibodies like trastuzumab, leveraging U.S. penetration and pricing strategies. Celltrion pioneers with vertically integrated production, expanding via partnerships in Europe. Dr. Reddy's and Biocon focus on emerging markets, offering affordable options through licensing. Other players like Teva, STADA, Apobiologix, Intas, and BIOCAD contribute via regional dominance and co-development. These firms engage in M&A, R&D investments, and stakeholder education to maintain shares, with fragmentation in Asia allowing niche opportunities.

Oncology Biosimilars Market Historic and Future Pathway Analysis:

Historically, from 2020 to 2024, the oncology biosimilars market expanded due to patent expirations, regulatory advancements, and cost pressures, with monoclonal antibody biosimilars like trastuzumab gaining traction in developed markets. Growth was marked by improved manufacturing and approvals, transitioning from skepticism to acceptance. The market size grew steadily, setting the stage for acceleration. Looking ahead to 2025-2035, expansion will be driven by new biosimilars for additional indications, manufacturing enhancements, and personalized medicine, extending to emerging regions.

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Oncology Biosimilars Industry News:

Recent developments highlight the oncology biosimilars market's momentum. In July 2025, biosimilar approvals accelerated, reshaping healthcare with price reductions in oncology drugs like trastuzumab and bevacizumab. ICON's insights noted biosimilars achieving 53% market share across treatments, driving cost savings. January 2025 saw a wave of biosimilars targeting blockbusters, promising broader access. Samsung Bioepis' Q1 2025 report showed significant oncology biosimilar gains.

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