# Biosimilars Beyond Borders

*Why Emerging Markets Need Local Strategies for Biosimilar Trials*

The global biosimilar market is expanding faster than ever. Driven by the need for affordable biologic therapies and a growing number of expiring patents, biosimilars are reshaping how patients access advanced treatments.

According to ***MarketsandMarkets (Jun, 2025)***, the global biosimilar market, valued at US$ 32.75 billion in 2024, stood at US$ 35.04 billion in 2025 and is projected to advance to a resilient Compound Annual Growth Rate (CAGR) of 7.5% from 2025 to 2035 culminating in a forecasted valuation of US$ 72.29 billion by the end of this period. Biosimilars are at an exciting time of their development for the great benefit of patients and healthcare systems across the globe as they significantly reduce expenditure and lead to opportunity for diversified investments in the health sector.

When generic drugs were first introduced, their market share was nearly zero, but it began to grow slowly as patent expirations on key drugs occurred, governments sought to reduce healthcare costs and regulatory framework or market infrastructure to support generic competition improved. Since, according to a ***2020 Intercontinental Market Services report***, generic drug penetration in emerging markets has grown significantly in recent years and made up almost 91% of total prescription volumes in emerging markets. One can expect that biosimilars will follow the same trend.

Yet while Europe, the U.S., and parts of Asia have seen tremendous progress, a key challenge remains: **how do we successfully develop biosimilars in emerging markets?**

Too often, companies approach clinical trials with a "copy-paste" model — applying strategies designed for established regions without accounting for the unique realities of new markets. The result? Delays, regulatory bottlenecks, and missed opportunities to reach millions of patients who could benefit most.

At the heart of the solution lies one principle: **global science requires local strategy.**

## The Global Rise of Biosimilars

Over the past two decades, biosimilars have transformed healthcare economics. They've reduced treatment costs for chronic conditions like cancer, diabetes, and autoimmune diseases, while expanding patient access to life-saving biologics. ***Mulcahy AW, Hlavka JP, Case SR (Rand Health Q. 2018)*** estimated the biosimilars cost saving in the US to be $54 billion from 2017 to 2026.

Europe remains the most mature market, with over 80 biosimilars approved to date, while India and South Korea have demonstrated how local manufacturing and regulatory agility can drive both innovation and affordability.

However, emerging markets such as Africa, Latin America, and parts of the Middle East are now seen as the next frontier — not only as new markets for commercialization but as regions with growing potential for **research and development as well as manufacturing**.

There are clearly opportunities here for biosimilar drugmakers, both in cheaper manufacturing of biosimilars and a growing potential patient population. If we take cancer as a target, according to

the ***Force, Lisa M et al. (The Lancet, Volume 406, Issue 10512, 1565 - 1586)***, there were 4.33 million risk-attributable cancer deaths globally in 2023, comprising 41.7% of all cancer deaths. According to this report, it is estimated that in 2050 there will be 30.5 million cases and 18.6 million deaths from cancer globally, 60.7% and 74.5% increases from 2024, respectively. These forecasted increases in deaths are greater in low-income and middle-income countries 90.6% compared with high-income countries 42.8%

## Challenges in Emerging Markets

Despite the opportunities, the road to conducting biosimilar research in these regions is not straightforward.

**1. Fragmented regulatory frameworks.**
While some countries like Argentina, Brazil, Canada, Chile, China, Colombia, Ecuador, India, Japan, Malaysia, Peru, South Korea, and South Africa have adopted WHO-aligned biosimilar guidelines, others are still in the early stages of establishing clear pathways. This diversity can complicate research and development, regulatory submissions and approval.

**2. Infrastructure limitations.**

Many facilities lack the large-scale bioreactors and downstream processing equipment necessary for production, and limited space is a major constraint. In addition, cold chain requirements for biosimilars are a major barrier, potentially limiting patient access to drugs if the local supply chain cannot maintain the required temperatures. Lastly, scaling up production requires significant capital investment in new or larger facilities and equipment, which is a challenge for smaller and mid-sized manufacturers.

**3. Population and disease diversity.**
Emerging markets often have younger populations, different disease prevalence, and varied healthcare-seeking behaviors. These factors can impact recruitment strategies and data interpretation. However, disease diversity can be an opportunity for bio similar development as they are used to treat a wide range of complex conditions, such as cancers, autoimmune diseases, and diabetes, that were previously hard to treat or inaccessible due to the high cost of the original biological medicines.

**4. Cultural and communication barriers.**
Public awareness of clinical research and biosimilars remains limited, and misconceptions can hinder patient enrollment and retention. Though there are no grounds, there are beliefs that the use of a biosimilar carries more risks and is less effective than the corresponding reference product.

**Did you know?**
To approve a biosimilar, totality of evidence is considered and this includes pharmacokinetic/ pharmacodynamic as well as efficacy studies. If we take Africa for instance, the continent accounts for over 17% of the global population but less than 2% of global clinical trials — a gap that represents both a challenge and an opportunity especially for compounds as new as biosimilars.

## Why Local Strategies Matter

Global biosimilar standards are essential, but **localization** is what turns a global vision into practical success. Companies that invest in understanding and adapting to local conditions are the ones that achieve both scientific and operational excellence.

Here's why local strategies make the difference:

**1. Regulatory alignment from the start.**
Engaging early with local authorities helps anticipate country-specific requirements and streamline approvals. Harmonization efforts across African regions, for instance, are accelerating, but proactive dialogue remains crucial.

**2. Strategic partnerships.**
Collaborating with local hospitals, universities, and CROs strengthens study feasibility and ensures compliance with national ethics standards. These relationships also build long-term credibility for sponsors.

**3. Capacity building.**
Training local investigators, site staff, and regulators in biosimilars enhances the region's clinical research ecosystem — creating sustainable impact beyond single studies and programs.

**4. Patient engagement.**
Cultural sensitivity and community outreach improve trust and participation. Explaining what a biosimilar is, why it's safe, and how participation benefits local healthcare can make all the difference in research and development, recruitment success, approval and uptake.

**Key takeaway:**
Local expertise isn't a "nice-to-have." It's a competitive advantage.

## Case in Point: A New Paradigm for Africa

Across Africa and other emerging regions, a new model is taking shape — one built on **partnership and affordability**.

Companies that combine international quality standards with local operational expertise are proving that it's possible to conduct biosimilar trials efficiently and ethically in emerging markets.

For example, organizations like **BioSen Pharma** work with global sponsors to design and execute clinical development programs that leverage local knowledge, reduce costs, and strengthen regulatory compliance. By doing so, they enable sponsors to expand their reach while investing in the regions where access to affordable biologics is most needed.

This model doesn't just make research and development possible — it makes them sustainable.

## Building a Sustainable Ecosystem

Beyond individual studies, localized strategies contribute to the broader development of healthcare systems.

- **Strengthened infrastructure:** Each trial helps upgrade hospitals, laboratories, and monitoring systems.

- **Skilled professionals:** Training programs create a new generation of clinical researchers and regulatory experts.

- **Trusted processes:** Transparent engagement with ethics committees patients and healthcare professionals build long-term confidence in biosimilar clinical research.

The ripple effect goes far beyond biosimilars. It establishes a foundation for **innovation, education, and equitable access** across the healthcare continuum.

## Conclusion: Global Access Starts with Local Expertise

The biosimilar revolution is global — but access, trust, and success are local.

Emerging markets cannot be afterthoughts in clinical development. They are essential partners in shaping the future of affordable medicine. Sponsors, biotech, pharmaceutical companies and investors that recognize this early and invest in localized, culturally adapted strategies will not only meet regulatory and scientific requirements — they will help redefine global healthcare equity.

“The future of biosimilars lies not in copying what worked elsewhere, but in creating new models that work where the need is greatest.”

At **BioSen Pharma**, we believe that by bridging global science with local expertise, we can make biosimilar innovation truly borderless — bringing high-quality, affordable biologics to every corner of the world.