hVIVO

A Science Led Drug Development Partner

OXFORD UNIVERSITY BIOTECH SOCIETY

Biosimilars: Shaping the Future of Biologic Care

World-leading expertise across specialist therapeutic areas, offering end-to-end clinical development solutions to a global client base

Delivering strategic insight and operational expertise to support rapid study start-up and reliable delivery

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Executive Summary

Biosimilars are essential tools for expanding patient access to life-changing treatments and driving pharmaceutical innovation.
Numerous high revenue biologics covering a wide range of therapeutic areas are set to expire in the near future, presenting a unique opportunity for increased biosimilar development.

The global biosimilars market is entering a phase of strong growth and dynamic changes. Current projections indicate a compound annual growth rate (CAGR) of approximately 17.9% over the next five years, highlighting unique and evolving opportunities for biosimilar development and market expansion.

The main drivers of this transformative phase are the upcoming number of reference biologics expected to lose market exclusivity- *unlocking a major pipeline opportunity for biosimilar development*- coupled with the evolving regulatory frameworks to streamline and accelerate biosimilar development. These changes are intensifying competition, supporting healthcare system sustainability, and expanding patient access to life-changing therapies, positioning the market for sustained growth and innovation.

hVIVO is an scientific led drug development partner and a global leader in human trials, bringing together therapeutic expertise, multi-site capabilities, clinical research units, volunteer recruitment, specialist bioanalytical services, consultancy services, and biometry services.

With its fully integrated specialist service, hVIVO is a strong strategic partner for active biosimilar developers and players seeking support in expanding in this space.

This whitepaper explores the current market dynamics, the recent regulatory shifts and chemistry, manufacturing, and control (CMC) considerations supporting rapid biosimilar development, pipeline status, and market sustainability in Europe. It highlights the unmet needs and evaluates the opportunities and strategic implications for stakeholders.

> **To unlock the full potential of biosimilars, stakeholders will be required to leverage scientific innovation, collaboration, and strategic opportunity.**

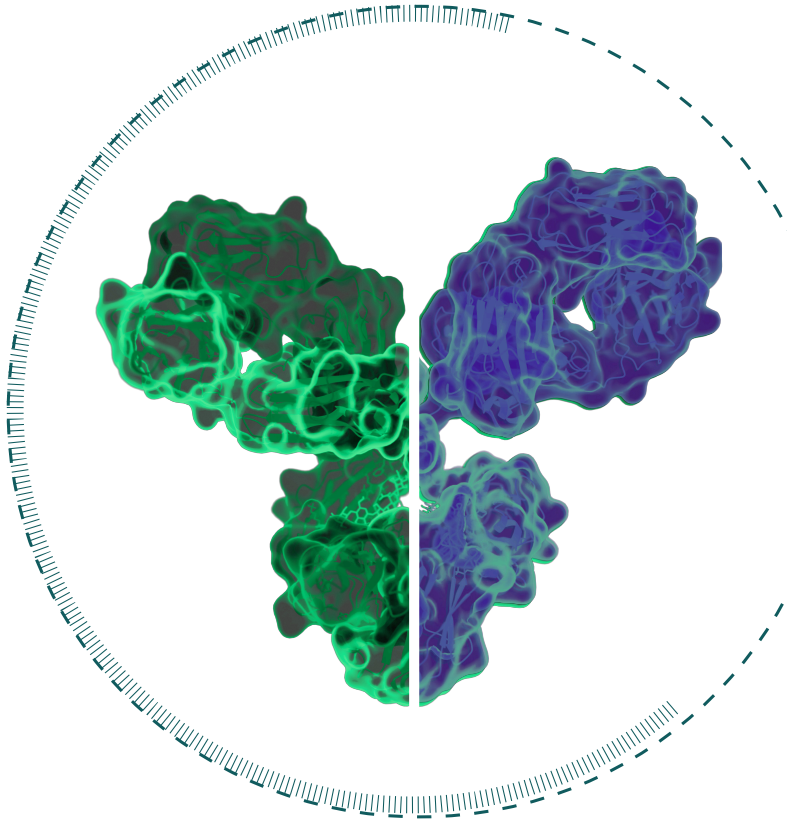
Biosimilars: Shaping the Future of Biologic Care

Biologics have revolutionised the treatment of chronic diseases such as cancer, diabetes, inflammatory and autoimmune disorders, accounting for almost half of total medicine spending money in US and Europe since 2023. Their high costs continue to limit patient access globally. Once the more expensive original biological product loses patent protection, biosimilars address this challenge by offering comparable clinical safety, quality and efficacy at a lower cost.

Biosimilars are highly similar versions of an already approved biologic. These are large, complex drugs, such as monoclonal antibodies, insulin, growth hormones.
They both contain the same active ingredient but due to the complex nature of biologics derived from living organisms, they cannot be produced as exact molecular replicas, adding a small degree of expected variability.
They are designed to maintain comparable clinical safety, quality, and efficacy as their reference biologic and are approved for the same indications supported by robust CMC comparability. The development process for biosimilars requires less time and capital investment, enabling a more sustainable and scalable access to biologic therapies[1,2,3].

While oncology and immunology biosimilars continue to lead the market, other therapeutic areas, specifically gastroenterology, endocrine, metabolic, and cardiovascular have also experienced strong growth in recent years, a trend that is expected to continue with the upcoming loss of exclusivity events[4].
Notable biosimilars that have transformed the treatment of biologic care include TNFα inhibitors for chronic inflammatory conditions such as Adalimumab (Humira) and Infliximab (Remicade), targeted oncology drugs such as Bevacizumab (Avastin) and Trastuzumab (Herceptin), and biosimilars for the treatment of metabolic and endocrinology disorders such as Semglee (insulin glargine), Somatropin (human growth hormone) and Denosumab (osteoporosis)[5].

> **Biosimilars are becoming increasingly recognised beyond their role as cost-effective alternatives, emerging as solutions for expanding patient access to treatments, driving innovation and reshaping the global pharmaceutical landscape.**



Biosimilar Market Growth and Dynamic Changes

The biosimilars market is entering a phase of strong growth and dynamic changes. Valued at $30.3bn in 2024, it is projected to grow significantly in the next 5 years with a CAGR of 17.9%, reaching as high as $114.20bn by 2031[4,6].

This growth is driven by the global demand for cost-effective alternatives, streamlined regulations, a major wave of biologics coming off patent in the near future, and increasing opportunities for strategic partnerships to support biosimilar development processes including early CMC alignment. However, challenges in manufacturing, competition and pricing pressure, limited biosimilar pipeline development, and patent litigation persist[7,8]. Addressing these challenges requires a collaborative effort across stakeholders to untap the upcoming major opportunity for biosimilar development and expand treatment access globally.

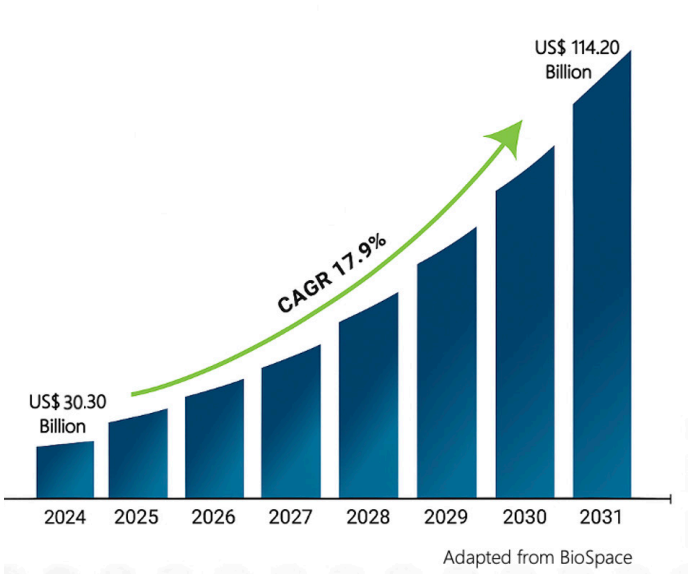


Figure 1: Economic forecast and compound growth projection rate for the biosimilars market (2024-2031)[6]. US$Billion.

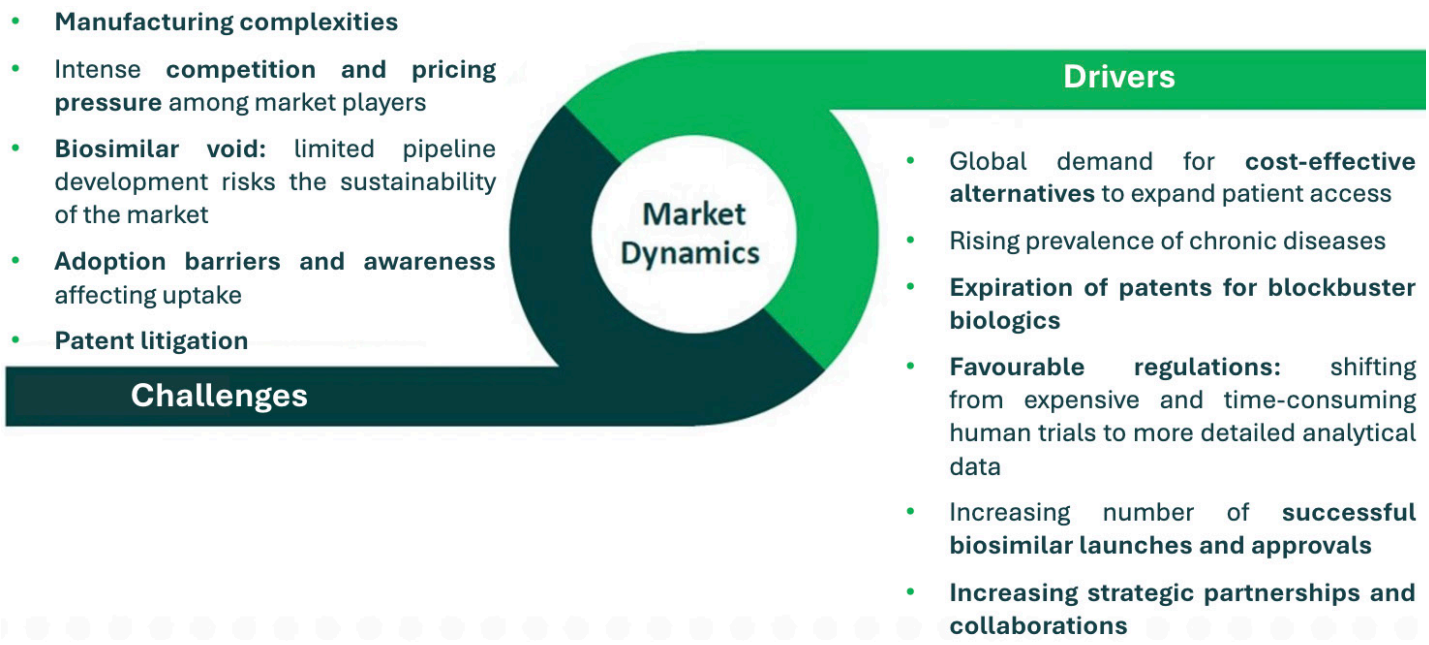


Figure 2: Biosimilar market dynamics highlighting the factors driving the rapid growth of the market and challenges to overcome to enable long-term market sustainability.

Regulatory Landscape Shifts and Implications for Biosimilar Development

Biosimilar regulation has long been grounded in the principle of "totality of evidence." Recent regulatory updates reflect a recalibration of how that evidence is weighted. Advances in analytical technologies and clinical pharmacokinetic (PK) and pharmacodynamic (PD) methodologies have increased confidence in clinical pharmacology data as highly sensitive indicators of biosimilarity.

Advanced analytical characterisation together with PK/PD studies are now regarded as highly sensitive indicators of biosimilarity. These studies have the potential to provide robust early evidence and strong scientific justification which reduces the inherent need for comparative efficacy trials.

A Unifying Regulatory Convergence Toward PK/PD-Driven Biosimilar Development

Across leading regulatory authorities, recent guidance updates reflect a shared move toward streamlined, analytically led development pathways, with clinical PK/PD evidence placed at the centre of biosimilar evaluation[9,10,11].

United States – FDA Draft Guidance (October 2025):

Reduces reliance on routine comparative clinical efficacy studies, reinforcing clinical pharmacology as a primary driver of regulatory confidence. Any uncertainty is expected to be addressed through sensitive PK and targeted immunogenicity assessments[10,12].

United Kingdom – MHRA Updated Guidance (February 2025):

Places clinical pharmacology studies as the central clinical component of biosimilar evaluation within the UK regulatory framework, with analytical evidence supported by appropriately designed PK studies often sufficient to establish comparable immunogenicity[11].

European Union – EMA Draft Reflection Papers (2025):

Continues to support reduced reliance on comparative efficacy trials, favouring streamlined development centred on strong clinical pharmacology data. Maintains the importance of comparative clinical PK studies while allowing flexibility in study design, including consideration of single-dose vs multiple-dose approaches and the integration of immunogenicity parameters[9,13].

The biosimilar regulatory environment is now defined by convergence, efficiency, and scientific rigour. With FDA, MHRA, and EMA guidance aligned around analytical comparability and PK/PD evidence, clinical studies assessing PK comparability have become the decisive factor in biosimilar success.

Drug development partners with proven expertise in controlled, high-quality PK/PD research will play a critical role in enabling faster and more efficient biosimilar development in this evolving landscape

Strategic Implications for Biosimilar Developers

- *Front-Loaded Evidence Generation:* Biosimilar development programmes must ensure high-quality analytical and PK/PD comparability data to maximally benefit from the streamlined regulatory pathways. Suboptimal demonstration of comparability evidence risks triggering additional clinical requirements later in development, making it vulnerable to competition.
- *Increased Sensitivity Requirements:* PK/PD studies must be sufficiently sensitive to detect subtle differences between biosimilar and reference products. This requires optimised study designs, intensive sampling strategies, and robust bioanalytical methodologies
- *Importance of Controlled Clinical Environments:* Minimising variability through highly controlled clinical settings is critical to maximise data quality and strengthen regulatory confidence in findings.

Regulatory Shifts Directly Align with hVIVO's Established Strengths in Clinical Pharmacology Research

- *Intensive PK Sampling:* Ability to conduct highly sensitive PK/PD studies with dense sampling schedules.
- *Controlled Clinical Environment:* Reduction of inter- and intra-participant variability enhancing data quality.
- *Deep PK and Clinical Pharmacology Expertise:* Leveraging non-clinical and clinical capabilities to design and execute complex biosimilar studies.

These regulatory shifts place unprecedented importance on the design and execution of clinical PK/PD studies. As clinical pharmacology becomes the central pillar of biosimilar development and regulatory evaluation, drug development partners such as hVIVO are well positioned to support sponsors navigate this new regulatory landscape.

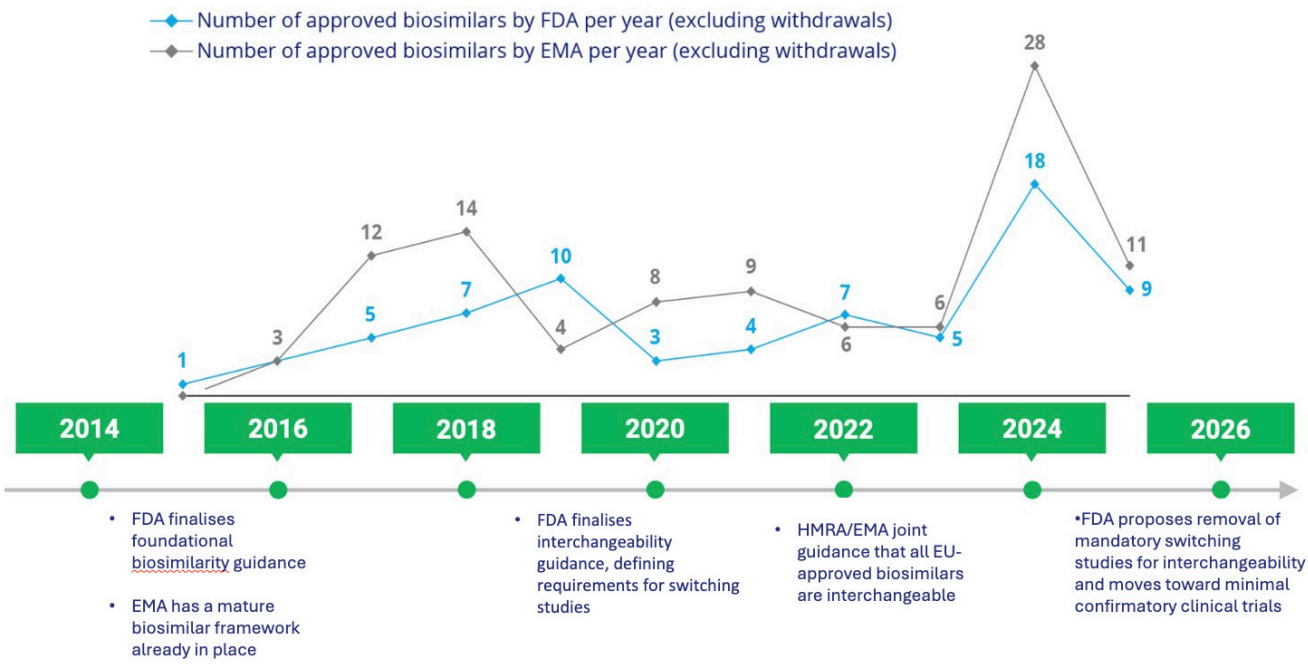


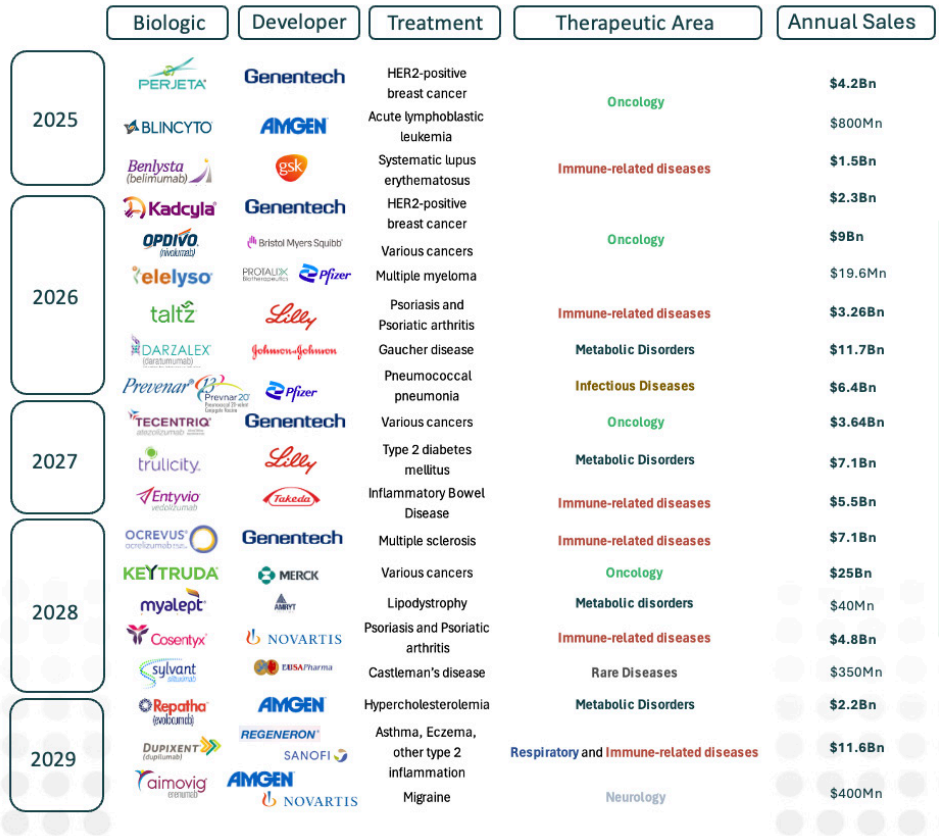
Figure 3: FDA and EMA biosimilar approvals and main regulatory changes throughout 2015-2025[4].

Biosimilar Pipeline Status and Market Sustainability in Europe

Nearly 200 drugs are going off patent in the near future, including at least 69 blockbusters (>$1bn in annual sales). This upcoming patent cliff includes a significant number of biologics, presenting a major opportunity for biosimilars development in diverse therapeutic areas.

Over a dozen blockbuster biologics are expected to lose exclusivity over the next decade, with major expiries concentrated across oncology (24%) and immunology (11%), including multiple checkpoint inhibitors- which are key drivers of spending[14]. Endocrine and metabolic, gastroenterology, and cardiovascular indications have also been driving market growth in recent years, a trend expected to continue as additional patents expire across these therapeutic areas[4].

There is an expected growth in the market targeting off-patent metabolic biologics, driven by the upcoming loss of exclusivity of high-value biologics used to treat diabetes and other metabolic conditions (Darzalex, Trulicity, Myalept, Repatha)[15,16,17].



hVIVO provides first-in-class expertise across specialised therapeutic areas- including endocrine and metabolic, gastroenterology, cardiovascular, dermatology, respiratory, infectious diseases, and haematology offering end-to-end clinical development solutions

Figure 4: Pipeline of biologics coming off patent in the near future in diverse therapeutic areas. Annual sales data from 2023/2024[15,16,17].

Major opportunity for cost savings from biosimilars remains untapped.

Around €30bn worth of biologics will lose market exclusivity (LoE) in Europe in the next decade. Over 70% of these biologics currently have no biosimilars pipeline in Europe[14].

This represents the "biosimilar void" which is driven by:

- High development costs and regulatory hurdles
- Low projected return on investment
- Slow pace of streamlining regulatory and pricing/reimbursement policies across EU

Every stakeholder must address the gap in biosimilar development over the next decade.

Integrated CRO engagement can overcome these barriers by reducing cost, accelerating development, and enabling rapid market entry and value capture across multiple therapeutic areas.

Decline in new biosimilar competition could lead to billions in lost healthcare savings (minimum €15Bn) and reduced patient access.

The majority of upcoming LoE events are for low-value biologics (<€500mn annual sales). These may not be blockbuster drugs, but collectively they account for nearly €7bn in spending. Of the LoE biologics with annual sales over €500 million, nearly 30% have no biosimilar in development, accounting for nearly €8bn of missed opportunity.
The current biosimilar pipeline is primarily targeting high-value biologics expected to have greater than €1Bn in annual sales, compromising market sustainability[14].

By fostering collaboration and strategic partnerships with specialised CROs, along with the momentum generated through regulatory streamlining, sponsors can unlock development opportunities in therapeutic areas with historically limited clinical investment.

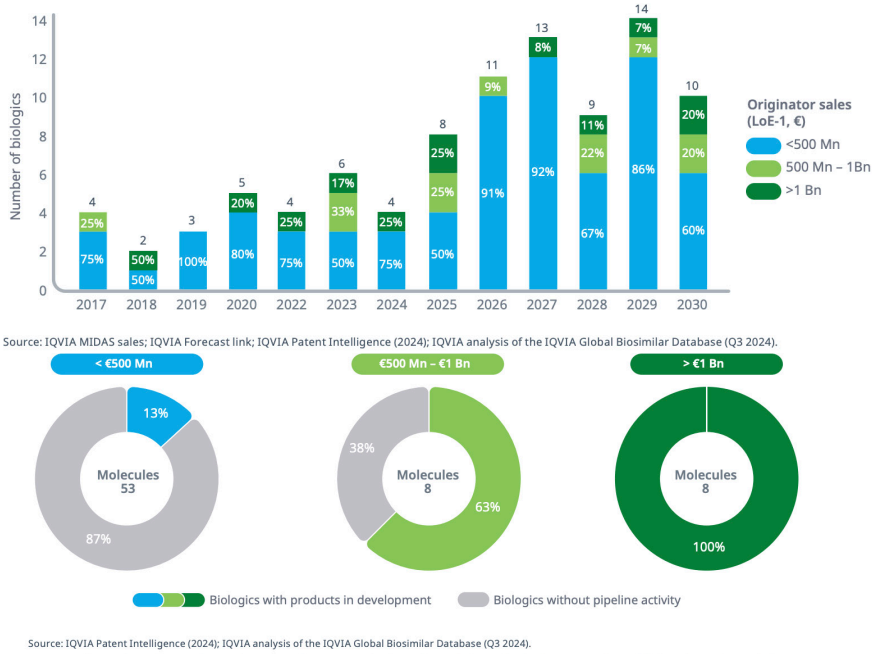


Figure 5: Biosimilar pipeline status in Europe. Top graph illustrates the biologic LoE events, by peak originator European sales (LoE-1). Bottom graph represents forecast of biologic LoEs in Europe (2024–2030) and competitor development, by originator sales value. Analysis includes all biosimilars in development from pre-clinical pre-registered; excl. approvals. The data shown is accurate as of November 2024[14].

Biosimilar Success Starts with the Right Partnership

Leading pharmaceutical developers continue to signal strong confidence in the long-term growth of the biosimilars market through substantial investment. Sanofi has committed $500 million to Teva to strengthen its portfolio[18], while Sandoz - formerly part of Novartis - has announced $1.1 billion in biosimilar investment, including $440 million for a new manufacturing facility[19]. These investments reflect both sustained market growth and the increasing complexity of biosimilar development.

Successful biosimilar development is rarely achieved in isolation. Most small- and mid-sized pharmaceutical companies lack the capital, specialist infrastructure, and integrated capabilities required to deliver biosimilar programs end to end, making strategic partnerships essential[20,21]. This has driven sustained demand for CROs that can act as true development partners, offering clinical PK/PD expertise, integrated analytical and immunogenicity support, regulatory guidance aligned with EMA and MHRA expectations, and efficient, cost-controlled clinical execution.

The prevalence of joint ventures and collaborations across the biosimilars ecosystem - such as the Biogen-Samsung Biologics alliance[22] - demonstrates that partnership, rather than costly vertical integration, is often the most effective route to success. As biosimilar development increasingly concentrates in the EU and the US, specialist CROs embedded within these ecosystems play a critical enabling role.

hVIVO is uniquely positioned to fulfil this role. By partnering with hVIVO, developers gain immediate access to integrated clinical pharmacology expertise, scientific capabilities, regulatory guidance, and aligned CMC considerations - without the time, risk, or capital burden of building internal infrastructure or pursuing resource-intensive mergers and acquisitions. As a strategic drug development partner, hVIVO enables efficient, high-quality biosimilar development and represents a cornerstone of successful biosimilar programs.

> **Partnering with a specialist CRO is essential for successful biosimilar development, enabling developers to access critical expertise and infrastructure without the burden of costly vertical integration.**

hVIVO: Specialised Drug Development Partner Supporting Biosimilar Development

There are several world-leading service providers, such as Charles River, Eurofins, ICON, IQVIA, PPD, or SGS with a product portfolio covering the biosimilar market. These large CROs dominate late-phase clinical trial programs, however, the biosimilar landscape is rapidly evolving.
Recent regulatory shifts in FDA/EMA approvals open new opportunities for agile, specialised CROs, like hVIVO, who focus on clinical pharmacology comparability studies.

hVIVO's Portfolio in the Biosimilars Market

hVIVO is a global leader in human trials providing therapeutic expertise, multi-site capabilities, clinical research units, participant recruitment, specialist laboratory services, consultancy services, and biometry services.

hVIVO's integrated clinical development capabilities and strategic positioning enable efficient, targeted evidence generation for biosimilar developers in line with evolving regulatory expectations. This makes hVIVO a strong partner for biosimilar testing for both established and emerging biosimilar players.

How Does hVIVO Compare with Other Drug Development Partners in the Biosimilars Market

Several mid-sized EU CROs offer services comparable to hVIVO, with some already active in biosimilars, reflecting the growth potential of the market. However, the majority of competitors remain heavily focused on oncology, making it a highly saturated landscape.

hVIVO differentiates itself by providing core expertise in specific therapeutic areas, including endocrine and metabolic, gastroenterology, cardiovascular, dermatology, respiratory, and infectious diseases, thereby supporting long-term market sustainability. This breadth of therapeutic focus, combined with efficient participant recruitment and versatile clinical sites in Germany and London, enables hVIVO to integrate strategic insight with operational excellence and deliver a wide range of clinical studies across multiple locations.

> **hVIVO supports biosimilar development by providing human trials, world-leading expertise across specialist therapeutic areas, versatile clinics and end-to-end development capabilities.**

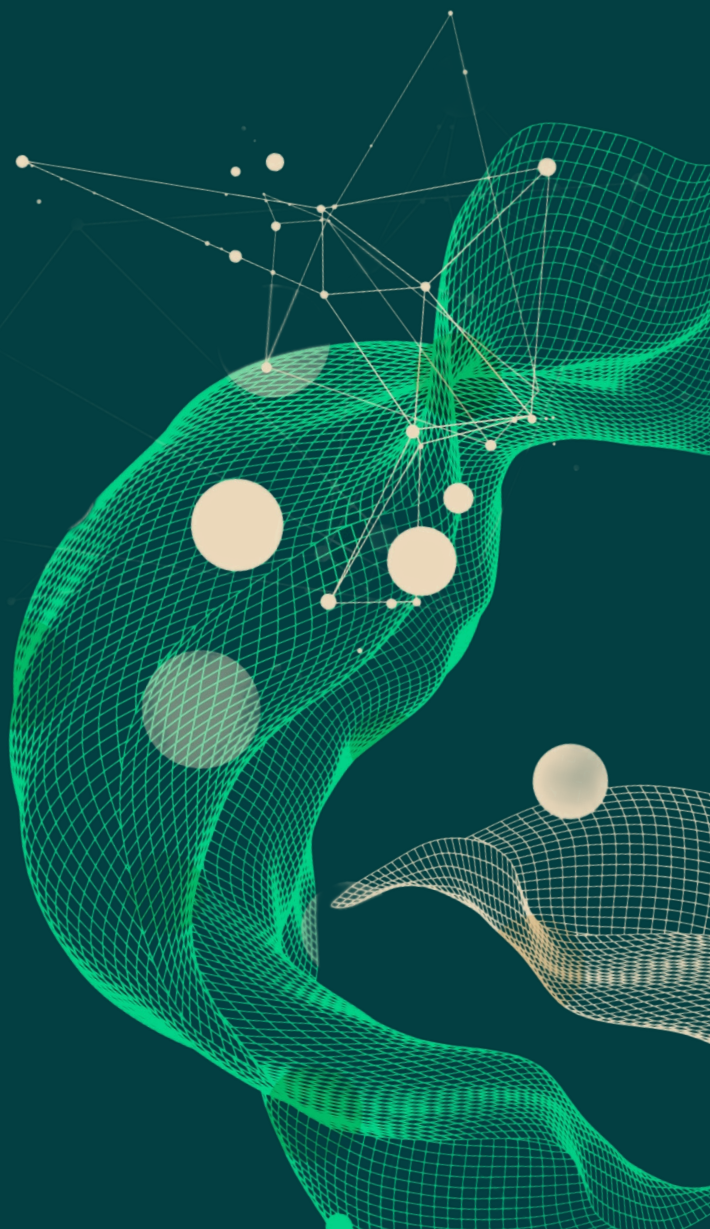
Planning for the Future: Considerations and Insights

The biosimilars market is rapidly evolving and requires stakeholders to foster collaboration in order to overcome the challenges in this market and unlock the full potential biosimilars offer.
A collective effort is required to leverage the momentum generated through further approvals and regulatory streamlining to tackle the unmet needs in biosimilar development over the next decade.

Market policies and dynamics are shifting in favour of increasing biosimilar development, opening opportunities for new competition and presenting a strong and strategic stage to enter this market.

Forward planning, early engagement with CROs, and decisive execution will be critical to ensure success in this market. As demand for accessible and affordable biologics continues to grow, specialised CROs such as hVIVO are uniquely positioned to identify strategic development opportunities and provide rapid and informed study execution, supporting successful entry into the biosimilars market.

As a science led drug development partner offering leading therapeutic expertise, consulting services, multi-site capabilities, clinical research units, and participant recruitment, hVIVO positions itself as a strong strategic partner for active biosimilar developers and players seeking to expand in this space.



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