Whitepaper

The future of oncology biosimilars:
Considerations for development through 2040

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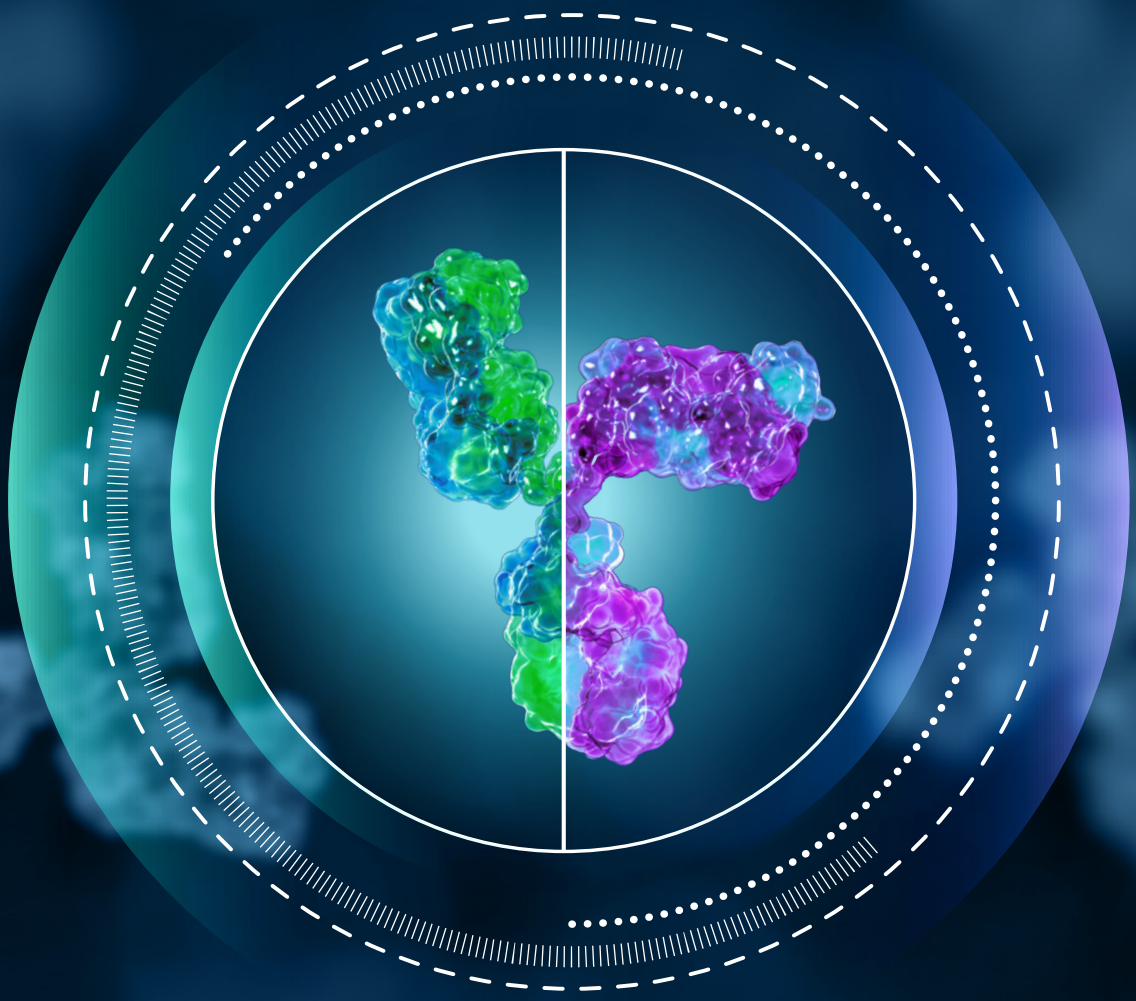

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Executive summary

Biosimilars have emerged as a significant boon for improving access to cancer treatments for the more than 19 million people diagnosed each year. And as numerous patents for cancer biologics are set to expire through the year 2040, opportunities for developers to use them as reference products for new biosimilars development are abundant.

With the speed of evolution of biologic cancer treatments, as well as regulatory guidance for biosimilars, the biosimilar development process must evolve as well. As numerous cancer biologics reach patent expiration, understanding how the development of oncology biosimilars is likely to shift will be critical for sponsors. This whitepaper will explore key considerations for developing oncology biosimilars and a forward-looking view of their evolution over the next fifteen years.

Read the whitepaper to explore:

- The cancer biosimilars patent and market landscape
- Current regulatory requirements and likely regulatory shifts
- Considerations for drug modalities such as monoclonal antibodies, bispecific antibodies, antibody-drug conjugates and CAR T therapies
- Hurdles and strategies for encouraging biosimilar adoption
- New technologies and methods in post-market monitoring

The role of biosimilars in cancer care

Finding effective treatments for cancer is one of the great undertakings of modern medicine – and one that has seen progress in leaps and bounds. In addition to traditional chemotherapies, biologics—medicines derived from living cells—have emerged as powerful treatment options. However, access to these lifesaving therapies can be challenging or restrictive for patients, largely due to high costs. With more than 19 million people around the world diagnosed with cancer every year,[1] this creates an urgent need for more accessible treatments.

Biosimilars are products created to closely emulate the mechanism of action, safety and efficacy of reference biologic products for which the patents have expired. With lower development costs than original biologics and a corresponding lower price tag, they increase accessibility by providing options for patients to receive a treatment with no clinically significant differences at a much more affordable price. By some assessments, wholesale acquisition prices for oncology biosimilars tend to be 10% to 25% lower than their reference products, but average sale prices for individual products can be as much as 66% lower.[2]

Additionally, high cancer care costs can have a major impact on healthcare budgets and funding, particularly as improved cancer detection and survival mean that treatment lasts longer.[3] Reduced costs resulting from biosimilar use has the potential to lower oncology spend in health plans and save health systems significant expenses. For instance, one analysis estimates that biosimilars could save the United States (US) healthcare system $54 billion over the course of a decade.[4]

The development of biosimilars is not without challenges, though. Unlike generic versions of small molecule drugs, biosimilars aim to replicate a biological product — but creating a completely identical biological product is impossible. This imposes unique requirements on the biosimilar development process. As another consideration, there are a number of modalities for biologics that must each be approached differently.

With the evolution of biologic cancer treatments and regulations for biosimilars, the biosimilar development process must evolve as well. As numerous cancer biologics reach patent expiration, it will be crucial for sponsors to understand how the development of oncology biosimilars is likely to shift.

This whitepaper will explore key considerations for developing oncology biosimilars—such as the patent landscape, regulatory concerns, modality-specific development and post-market monitoring—and a forward-looking view of their evolution over the next fifteen years.

An overview of the oncology biosimilars landscape

When considering biosimilar development in the cancer market, sponsors need to carefully evaluate the opportunities and challenges expected in the coming years. While the near future holds significant promise, several important factors must be considered.

Understanding the scope of upcoming patent expirations is integral to assessing the future of biosimilars in any indication, including oncology. Over the next fifteen years, there are a large number of cancer-related biologics with patents set to expire. These include a wide variety of oncological indications, including: melanoma, leukaemia, multiple myeloma, colorectal cancer, bladder cancer, breast cancer, liver cancer, non-small cell lung cancer and others.

Although the expiration of patents provides an opportunity for drug developers, not all are ideal for biosimilars, since advances and new findings have rendered them of limited benefit and unlikely to be profitable candidates. For example, necitumumab (brand name Portrazza) was originally approved for the treatment of squamous non-small cell lung cancer, but is no longer recommended due to its toxicity and limited efficacy compared to other therapeutic options.[5] Nevertheless, among these expiring patents are several noteworthy cancer therapies, such as Enhertu, a highly successful HER2-targeted, antibody-drug conjugate, which holds a re-examination exclusivity in Japan that is set to expire in 2033. Sponsors must weigh the success of a biologic and the relative success its biosimilar is likely to have when selecting a direction for development.

Understanding the commercialisation of a biosimilar is critical. These therapies walk a fine line for return on investment: While the development and approval process is shorter and less expensive than that of a novel biologic, it is still significantly more costly than for small molecule drugs. Additionally, one of the chief draws of biosimilars for patients and providers is their low-cost relative to their reference product, placing a limit on potential revenue. Therefore, it is imperative to create a strong commercialisation strategy that includes a compelling value proposition that will resonate with payers, a clear pricing approach and a targeted plan to reach patients and providers.

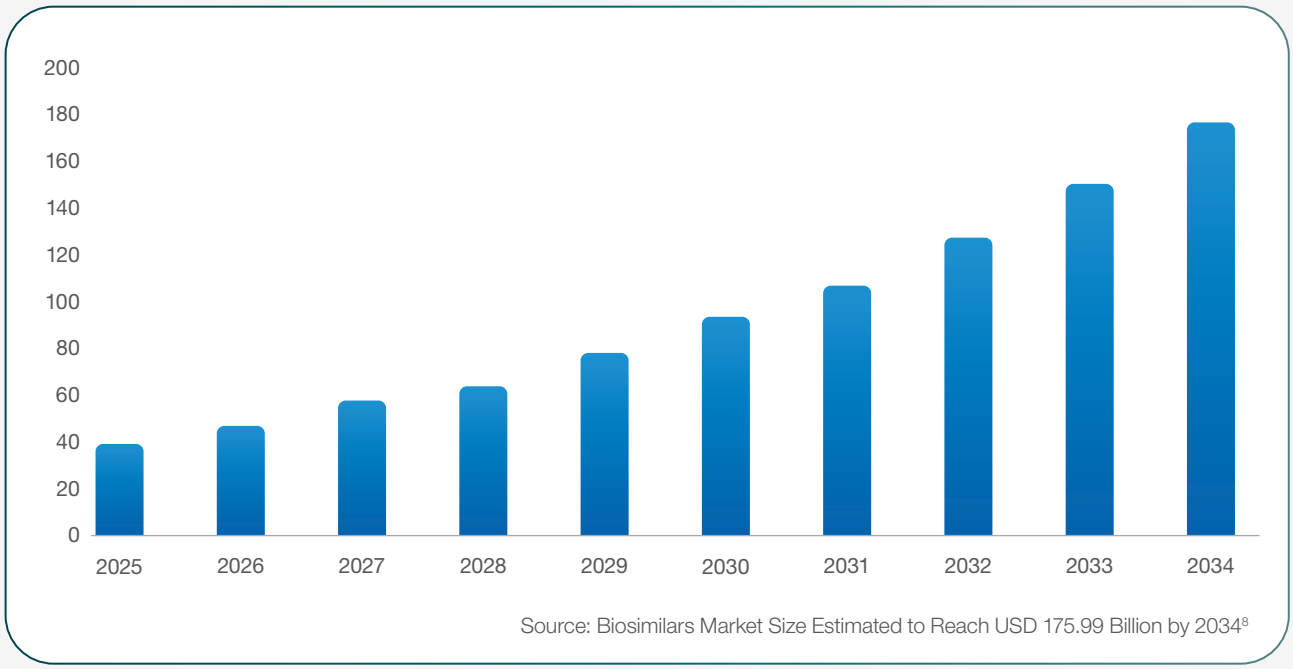
It is, nevertheless, possible for strategically developed and planned biosimilars to achieve significant success, particularly for those that enter the market early. The success of rituximab biosimilars, an anti-CD20 monoclonal antibody used to treat cancers such as non-Hodgkin lymphoma and chronic lymphocytic leukaemia, is an excellent example of the potential for oncology biosimilars. Within four years of entering the US market, biosimilars accounted for 41% to 61% of rituximab claims paid by Medicare and Medicaid and as of the end of 2024, biosimilars made up 76% of the rituximab market.[6,2]

The economic forecast for the biosimilars market is extremely positive. While exact estimates vary, analysts agree on the likelihood of strong growth.

Representative estimates include a 15.56% compound annual growth rate (CAGR) to reach a global market value of USD 121.88 billion by 2033, or a CAGR of 17.78% for a market value of USD 175.99 billion by 2034.[7,8]

As a result, sponsors have reason to be optimistic about the future of the biosimilars landscape.

Figure 1: Economic forecast for the biosimilars market | US$B



Source: Biosimilars Market Size Estimated to Reach USD 175.99 Billion by 2034[8]

Regulatory requirements for biosimilars

The European Medicines Agency (EMA) approved the first biosimilar, Omnitrope (somatropin, a recombinant human growth hormone), in 2006, setting a worldwide precedent and providing a framework that would help to shape biosimilar regulation globally.[9] The EMA and other influential authorities in biosimilar standards, particularly the U.S. Food and Drug Administration (FDA) and the World Health Organization (WHO) have established standards for biosimilar development and approval that many others have sought to emulate. As a result, while there may be regional differences, many regulatory pathways for biosimilars share the same or similar elements.

Biosimilars are unique from small molecule drugs in that, because of the natural variability of living cells and a complex manufacturing process, they cannot precisely replicate a reference product. To demonstrate that biosimilar investigational products are sufficiently similar to their reference biologics, regulatory submissions for initiating human clinical trials must include comprehensive data from manufacturing, analytical chemistry, and nonclinical studies. Traditionally, biosimilar development programs have involved a more abbreviated clinical pathway compared to originator biologics. Rather than conducting full Phase 1, 2, and 3 trials, global regulatory authorities generally require two types of clinical studies: a smaller pharmacokinetic sub-study (PKSS) followed by a single, larger comparative clinical study (CCS), although recent publications by EMA and FDA suggest there may be a shift in these clinical study requirements.

The first component of biosimilar development involves conducting analytical studies about the product's structure, quality attributes, manufacturing process and other such elements contributing to its composition. At this step, the goal is to establish high similarity with the reference product in its characterisation, as well as identify any differences and assess their potential impact. Each regulatory body has its own specific requirements for data at this stage, often depending on the specific therapeutic being evaluated.

Once analytical studies have been completed, the proposed product can advance to the preclinical stage, which primarily focuses on collecting pharmacokinetic (PK), pharmacodynamic (PD) and toxicology data. This may be conducted *in vitro* or, in some cases, may require *in vivo* studies when doubt remains regarding the safety of the proposed biosimilar. It should be noted that in the European Union (EU) and US, animal studies are only required in very specific cases and more often it is possible to gather the required data without their use.

Upon regulatory authority approval of the initial submission package containing this robust CMC and non-clinical data, biosimilar clinical development programs have involved a more abbreviated clinical pathway compared to originator biologics. Rather than conducting full Phase 1, 2, and 3 trials, global regulatory authorities generally require two types of clinical studies: a smaller pharmacokinetic sub-study (PKSS) — conducted in either healthy volunteers or patients, depending on the product — followed by a single, larger confirmatory comparative clinical study (CCS).

The purpose of a pharmacokinetic sub-study (PKSS) in biosimilar drug development is to compare the absorption, distribution, metabolism, and excretion (ADME) profiles of the biosimilar candidate to its reference (originator) biologic in humans. Specifically, a PKSS trial aims to;

- Demonstrate pharmacokinetic similarity to confirm that the biosimilar and the reference product have similar exposure in the body (AUC, Cmax, Tmax)
- Provide preliminary immunogencity assessments (ADAs nAbs), including identifying any early or unexpected immungenic responses that might indicate a clinically meaningful difference from the reference biologic
- Provide an early human data bridge as an initial clinical check that the biosimilar behaves similarly to the reference product in vivo, reinforcing findings from analytical and nonclinical data
- Inform the need for further clinical studies by determining whether the biosimilar meets pre-defined PK equivalence margins
- Meet regulatory requirements

A Comparative Clinical Study (CCS) may be required after submitting Pharmacokinetic Sub-Study (PKSS) results to provide direct evidence of clinical equivalence between a biosimilar and its reference product — especially when PK and initial immunogenicity data alone are insufficient to establish biosimilarity. A CCS directly compares the efficacy and safety of the biosimilar and reference product in patients with the intended condition. It is typically powered to show equivalence (not superiority or inferiority) in clinical endpoints such as response rate, and disease progression. It also often includes more robust immunogenicity monitoring over a longer time frame and larger patient population.

CCS trials are particularly required for complex biologics, where the mechanism of action (MoA) is not fully understood, there are multiple of poorly characterised targets, and/or the therapeutic indication is highly sensitive to minor structure or functional differences. Additionally, a CCS will be mandated by a Regulatory Authority when the analytical and functional similarity data leave residual uncertainty, if the biosimilar is first-in-class, or when extrapolation is sought, and in cases where PK/PD surrogates are not available or accepted as proxies for clinical outcome. Regulators may waive the CCS requirement if the biosimilar has extensive analytical similarity and matched PK/PD profiles, the MoA is well-characterised and sensitive biomarkers or surrogate endpoints are available, and there is a low immunogenicity risks and the reference product has a robust safety database.

Further, the FDA has unique requirements for interchangeability — a designation that allows pharmacists to substitute a biosimilar for its reference product without consulting the prescriber. This status requires more data than standard biosimilar approval. Initial regulatory guidance called for an evaluation of the safety and efficacy of switching between the reference product and the biosimilar.

However, new FDA draft guidance released in 2024 allows for the possibility that switching studies may not be necessary and permits applicants to provide an assessment of data that shows switching standards have been met.[10]

This change may potentially ease the burden on sponsors seeking to attain interchangeability status going forward. To date, the FDA has designated 13 biosimilars as interchangeable, primarily in the areas of diabetes, inflammatory diseases and retinal disorders.[10] Currently, no oncology biosimilars carry this designation and the US remains the only country to treat interchangeability as a legal classification.

> **It is worth noting that biosimilar development has experienced a marked boom in the Asia-Pacific region, including Australia, China, India, Japan, Singapore and South Korea. With such growth, this region is primed to become highly influential in the biosimilar market in the coming years.**

While some countries in the Asia-Pacific region, such as Australia and South Korea, are closely aligned with EMA and WHO regulatory standards for biosimilars, others vary significantly. For instance, China does not offer an abbreviated approval pathway. Sponsors interested in approval in this region should thoroughly investigate the differences in regulatory requirements to be prepared for the approval process.

Changes on the horizon

Biosimilar regulations are likely to evolve as our understanding of biosimilar development and biologic capabilities continues to improve. Fortunately, many of the likely changes to regulations that have been proposed are beneficial to the field. Many within the industry are advocating for a more streamlined regulatory approval process to encourage the development of biosimilars.

Current requirements have been criticised for unnecessary cost and complexity that hinders development — a particularly salient concern when one of the key advantages of biosimilars is their lower expense. This conversation and the identification of areas of redundancy in regulations, is pushing regulations to become more streamlined. Indeed, some regulatory bodies have already reevaluated some commonplace requirements.

For example, there is increasing evidence that comparative clinical studies do not add significant value compared to the extensive data analysis required and do not play a decisive role in biosimilar approval. The FDA and the United Kingdom's Medicines and Healthcare products Regulatory Agency have introduced provisions to waive comparative clinical studies for biosimilars and the EMA is considering the same.[11]

In fact, a reflection paper published by the EMA in April of 2025 suggests that a tailored approach for clinical development of biosimilars may be considered, in which comparative clinical studies may not be required for certain well characterised biosimilars, and pharmacokinetic data requirements —such as immunogenicity parameters—may be adjusted.[12] If this guidance is truly followed, the number of biosimilar trials being conducted is likely to increase and trials will be significantly truncated. As the industry accrues more information on what data is necessary to ensure safety, efficacy and biosimilarity, it is possible that further such streamlining of approval requirements will occur.

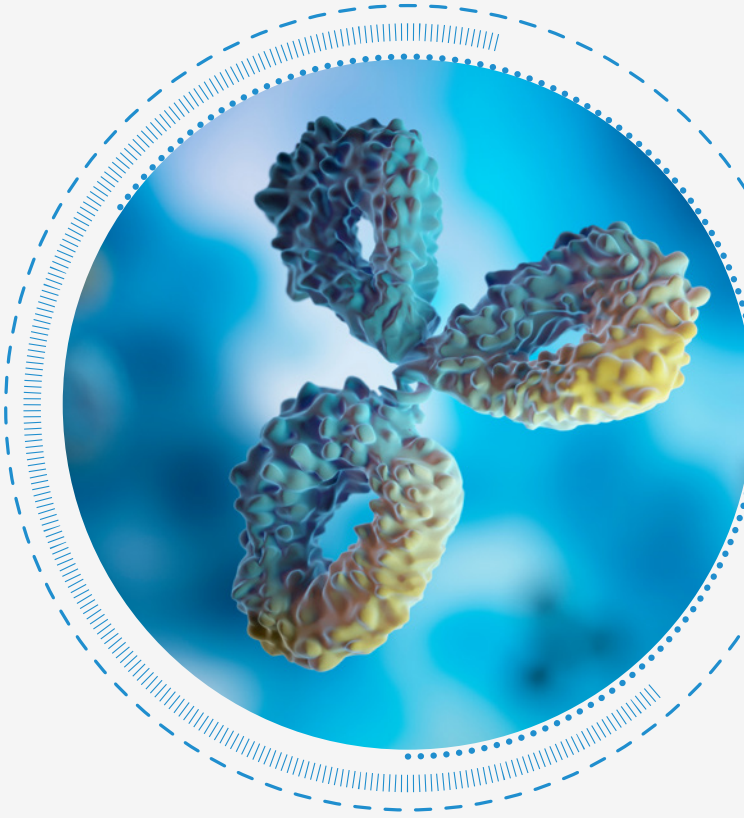
Additionally, there has been a push for increased international harmonisation of requirements to better facilitate bringing biosimilars to multiple markets. While regulations are broadly similar among leaders in the biosimilar sector, there are enough differences to complicate the process of achieving approval in multiple countries. Biosimilar developers must divert resources to meet differing national standards, while harmonised regulation would allow them to assemble a single set of submission materials. Not only would greater harmonisation benefit sponsors, but also the greater medical good, as it would provide better global access to high-quality, effective biosimilars. Many of the changes to international biosimilar regulations likely to occur in the foreseeable future will, as a result, move in the direction of greater harmonisation.

Trends and considerations for oncology biosimilar modalities

Biosimilars can span the full range of biologic modalities, each of which has its own unique concerns for development. As more advanced and complex cancer treatments are introduced, developing the corresponding biosimilars also becomes more challenging. This section will explore the prevalent modalities for oncology biologics with patents expiring in the next fifteen years and what sponsors should know about them.

Monoclonal antibodies

Through 2030, the prominent cancer biologics coming off patent are predominantly monoclonal antibodies (mAbs). Designed to target a specific antigen that is typically not expressed by healthy cells, mAbs can more precisely bind to cancer cells to interfere with cell signalling or flag them for targeting by the immune system.

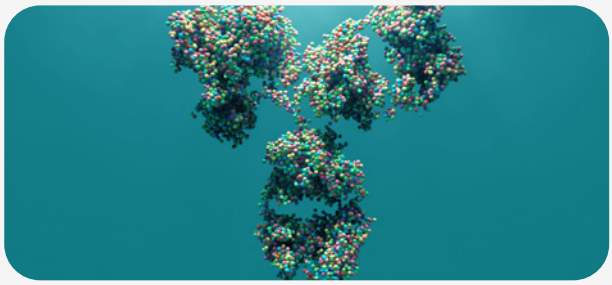


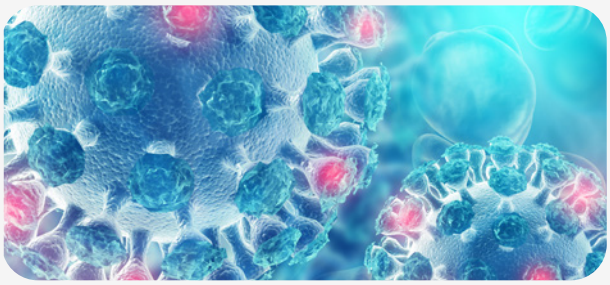
Biosimilar developers should be cautious of the potential for variability in manufactured mAbs, particularly in post-translational modifications, such as glycosylation, which can impact pharmacology or cause adverse events.[13] Additionally, any alteration in manufacturing sites or processes may affect the quality and pharmacology of mAbs through subtle, unintended variations in product characteristics—sometimes referred to as drifts—such as glycosylation patterns, potency, or structure. To ensure the continued quality and similarity of an mAb therapy, analytical assessments should be conducted throughout the therapy's lifetime.

Another concern for mAbs is their tendency to aggregation, in which proteins associate with one another to form large, tangled clusters, potentially leading to increased immunogenicity. Manufacturing processes should be designed carefully to reduce the formation of aggregates and purification techniques, such as ion-exchange chromatography, may be used to remove aggregates from the drug product.[14]

Advanced antibody-based therapies

Antibody-drug conjugates (ADCs) and bispecific antibodies (BsAbs) are emerging modalities with significant promise in oncology. Beginning in 2030, patent expirations for these advanced antibody therapies will become more frequent, making them a promising modality on the near horizon for biosimilars.





Antibody-drug conjugates

The mid-2030s are when ADC patent expirations escalate, particularly 2033 to 2034. These therapies are composed of an mAb conjugated to a cytotoxic drug through a chemical linker. With the antigen-binding specificity of an mAb, an ADC can deliver a cancer treatment directly to a tumour, avoiding much of the toxicity and damage to healthy tissue that comes with traditional chemotherapy.

Because they utilise mAbs, ADCs share many of the same considerations in development, such as the potential for aggregation and variability. Further, biosimilar ADCs will need to meet extensive, specific characterisation requirements to ensure that the complex structure is sufficiently similar to the reference biologic. This includes, but is not limited to, the drug/antibody ratio, the site of attachment location, the attachment of reaction by-products and the presence of free linkers.[15]

The complexity involved in the conjugation process makes ADCs a challenging target for biosimilar development. Despite this challenge, the development of biosimilar ADCs is not unprecedented: Ujvira, a biosimilar of the breast cancer ADC trastuzumab emtansine, was launched in India in 2021.[16] However, some within the industry have questioned whether this product was assessed using sufficiently rigorous standards to consider it a true biosimilar.

Bispecific antibodies

With patent expirations accelerating in the late 2030s into the 2040s, BsAbs are antibodies that target two distinct antigens or epitopes for binding, compared to a monoclonal antibody's ability to bind just one. By binding two separate antigens, BsAbs are better able to circumvent drug resistance—a serious concern with rapidly mutating cancer cells—while also minimising toxicity and off-target effects.

The more complex structure of BsAbs makes the stability and quality of the cell line critical to manufacturing, as the risk of abnormal protein folding and impaired function and safety is greatly increased in BsAbs compared to other antibody-based therapeutics. This complexity also raises development and testing costs, requiring more advanced assay development for analytical testing, as well as additional animal and human studies.

Highly involved preclinical work and analysis will be necessary for biosimilar BsAbs, including studies on PK/PD and immunogenicity. In fact, a major concern with BsAbs is their higher risk of immunogenicity due to multiple binding targets.[17] This may lead to patient reluctance to participate in clinical studies and provider reluctance to prescribe BsAb biosimilars.

Most development approaches for biosimilars reference regulatory authority expectations for mAbs and the lack of consistency for even that modality can lead to difficulty with any biosimilar submission. BsAbs are likely to be even more complicated. For instance, mAbs can often be automatically extrapolated to apply to all labelled indications upon biosimilar approval, which may not be the case for BsAbs.

Cell Therapy

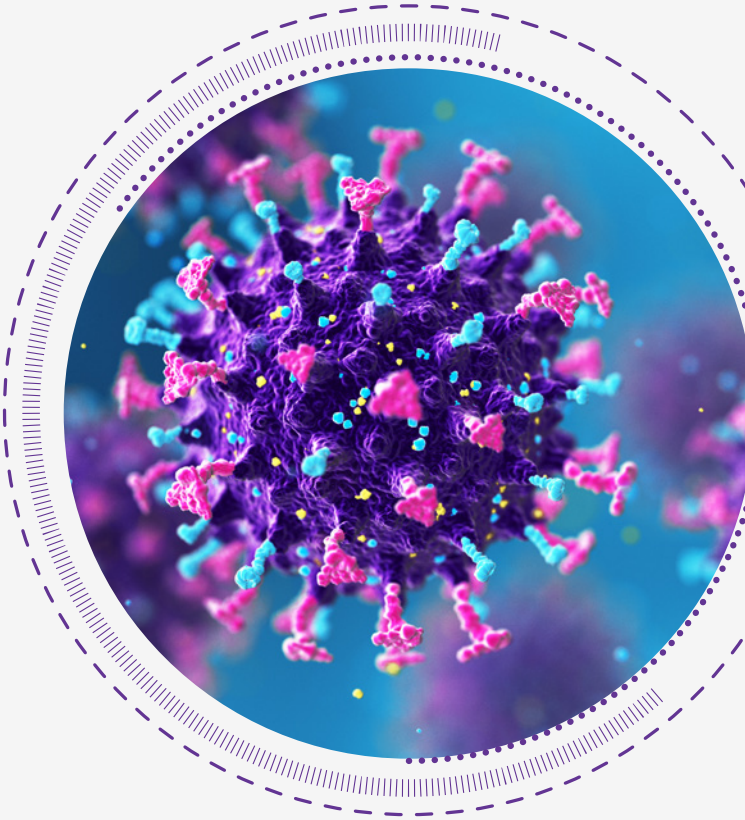
Of the modalities with patents expiring through 2040, the one with the least representatives is cell therapy. All of those expiring within the given time range are CAR T therapies, genetically modified immune cells that are engineered to target and kill a patient's cancer cells.

> **Cell therapies are still a relatively new technology with significant development challenges still remaining to be overcome and there is little to no precedent for biosimilars in this space**

As a result, it is difficult to be certain exactly what the approval process for them will be, if one is created at all. In all likelihood, it will be extremely challenging to meet the high standards of biosimilarity for a cell therapy, but it is theoretically possible.

Such an approval process will likely require more extensive clinical trials than those for a typical biosimilar product, to assess differences in immunogenicity — a concern for all biosimilars, but especially in the cell therapy space.

Biosimilar CAR T therapies, in particular, could be feasible if it can be demonstrated that the vector used for T-cell modification, along with subsequent cell characterisation, is sufficiently similar to that of the reference product.[18] However, the autologous nature of these therapies means that each treatment is inherently unique, making it difficult to prove similarity.



Navigating post-market concerns

Given the unique financial and regulatory position of biosimilars, the move into the market must be navigated very carefully. Sponsors should carefully consider their post-market strategy, particularly in regard to adoption and surveillance, to best enable the success of an oncology biosimilar.

Biosimilar adoption

A main concern for bringing biosimilars to market is encouraging adoption. As increasing numbers of biosimilars are approved and enter markets around the world, they will continue to be more accepted and utilised. However, there are still barriers that are likely to remain relevant for the foreseeable future and will take time and effort to overcome.

Systemic challenges

Adoption rates are higher in Europe compared to the US and in fact, Europe accounts for the largest portion of the global biosimilars market. This can be partially attributed to its long history with biosimilars, as well as a supportive regulatory framework and initiatives within many member states to promote biosimilar use. However, in the EU, differing healthcare systems and reimbursement policies among member states may cause disparities in adoption rates.[19] Sponsors should take these differences into consideration when seeking approval in the EU.

In the US, key barriers include reference products offering rebate programs or being placed in preferred positions on an insurance company's formulary. Indeed, insurance coverage is a major factor for access and uptake, making it critical to do as much as possible to reduce restrictions for a biosimilar's coverage. Thankfully for the oncology space, biosimilars for cancer treatment are less likely to have restrictions imposed upon them, as cancer treatments in general tend to be well received with favourable coverage.[20]

Additionally, the first approved biosimilar for a given reference product typically has fewer restrictions, most likely because the first entry tends to have had the time to collect plentiful real-world data (RWD) in support of it.[20] On top of safety and efficacy data, evidence of cost effectiveness can be influential, as it is significantly associated with less restrictive coverage — and when a reference biologic has not formally established its cost effectiveness, health plans tend to favour biosimilars.[20]

Patient and provider education

In the EU and US, physicians play a key role in patient use and access to biosimilars. When healthcare providers are unaware of, or reluctant to prescribe, biosimilars, it is unlikely that patients will use them. Some physician reluctance can be attributed to concerns about the nature of the products, such as the possibility of immunogenicity or reactions when switching a patient from a reference product to a biosimilar. Additionally, some are wary of biosimilars out of a misguided concern that the lower price and shorter approval process means less stringent standards for safety and efficacy.

As biosimilars have been on the market for some time, patient and provider awareness of them has increased and will likely continue to do so going forward.

> **Encouraging adoption is less a question of raising awareness of their availability than it is of addressing insufficient information and filling knowledge gaps.**

One method that may help increase trust is to conduct outreach and education on biosimilars. This can not only improve awareness and understanding but also help to make clear the rigorous standards for biosimilarity and approval. Having a stronger foundation of biosimilar knowledge, including safety and efficacy, enables physicians to be more confident and comfortable in prescribing them.

Another important method of encouraging biosimilar adoption is to collect robust post-market monitoring data that can provide evidence to support a biosimilar. Proving its safety and efficacy among broad populations and over longer periods of time, will be powerful in demonstrating that providers need not be hesitant to prescribe a biosimilar.

Continued monitoring

Continued safety monitoring of biosimilars following approval is a standard requirement, though specifics of this requirement may vary by regulatory body. These measures are intended to gather information about adverse events over long-term usage of a therapy and may call for a pharmacovigilance plan to be submitted at the same time a drug is submitted for regulatory approval. If a reference biologic has specific pharmacovigilance measures in place, sponsors of its biosimilar should plan to take those same measures, in addition to addressing any novel safety questions raised by the biosimilar itself.[21] In particular, immunogenicity is of distinct concern for any biologic, including biosimilars and should be specifically included in any ongoing monitoring efforts.

The future of post-market monitoring, however, does not solely lie in controlled trials or passive data collection. A growing tool for continued monitoring is RWD, which is likely to play an increasing role in post-market evaluation going forward. RWD refers to health data collected from outside of the controlled environment of clinical trials—for example, electronic health records (EHRs), medical claims data, or product or disease registries—and can potentially enable sponsors to analyse and evaluate a therapy's performance and safety signals among a broader population.

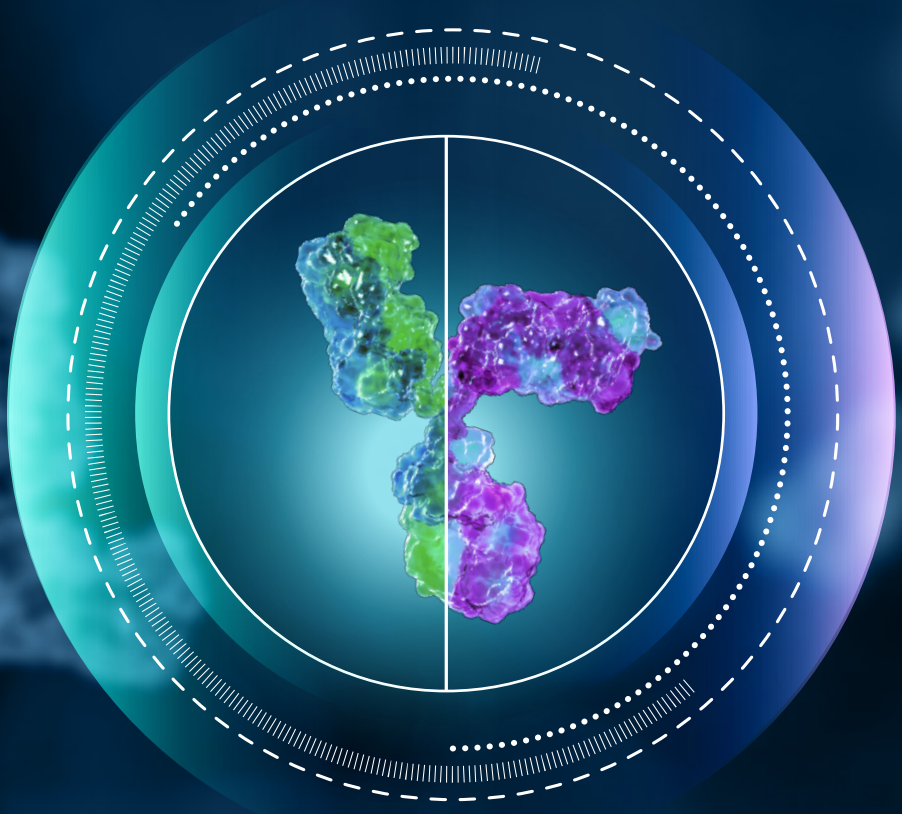
Advancing technologies are expanding the RWD capabilities available to sponsors. For example, as EHR interoperability initiatives increase the accessibility of medical data, it becomes easier to leverage them for RWD. Additionally, the development of advanced algorithms and artificial intelligence is enabling sponsors to more efficiently analyse the RWD that is collected and is transforming those insights into real-world evidence (RWE). RWE—insights about the usage, benefits, or risks of a medical product derived from RWD—can then be used to inform regulatory decisions, guide clinical practice and support market adoption.

The impact of RWD/RWE is already being demonstrated in clinical and regulatory contexts. For example, an Italian study analysed RWD from patients treated with biosimilar rituximab to support its clinical safety findings. The study showed that switching from the originator product to the biosimilar did not lead to an increase in adverse drug reactions, directly addressing a common concern.[22] Gathering this kind of data not only provides a more comprehensive view of a therapeutic's safety and efficacy in routine practice but also helps to generate RWE that can assuage patient and provider apprehensions. Looking ahead, it is entirely possible that sponsors will need to use RWD/RWE to stay competitive.

Planning for the future

The field of cancer biosimilars is evolving and will likely face many changes and challenges as newer modalities lose patents. Some areas, such as the broader geopolitical landscape and how it will impact the field of medicine as a whole, are in flux, making it difficult to predict what the long-term ramifications will be.

Nevertheless, many of the changes facing this field are foreseeable. Planning ahead, seeking out advice from an experienced clinical research organization and being prepared will be critical to giving oncology biosimilars the best chance at success. And given the need for accessible, affordable cancer treatments, that success has the potential to positively impact lives around the world.



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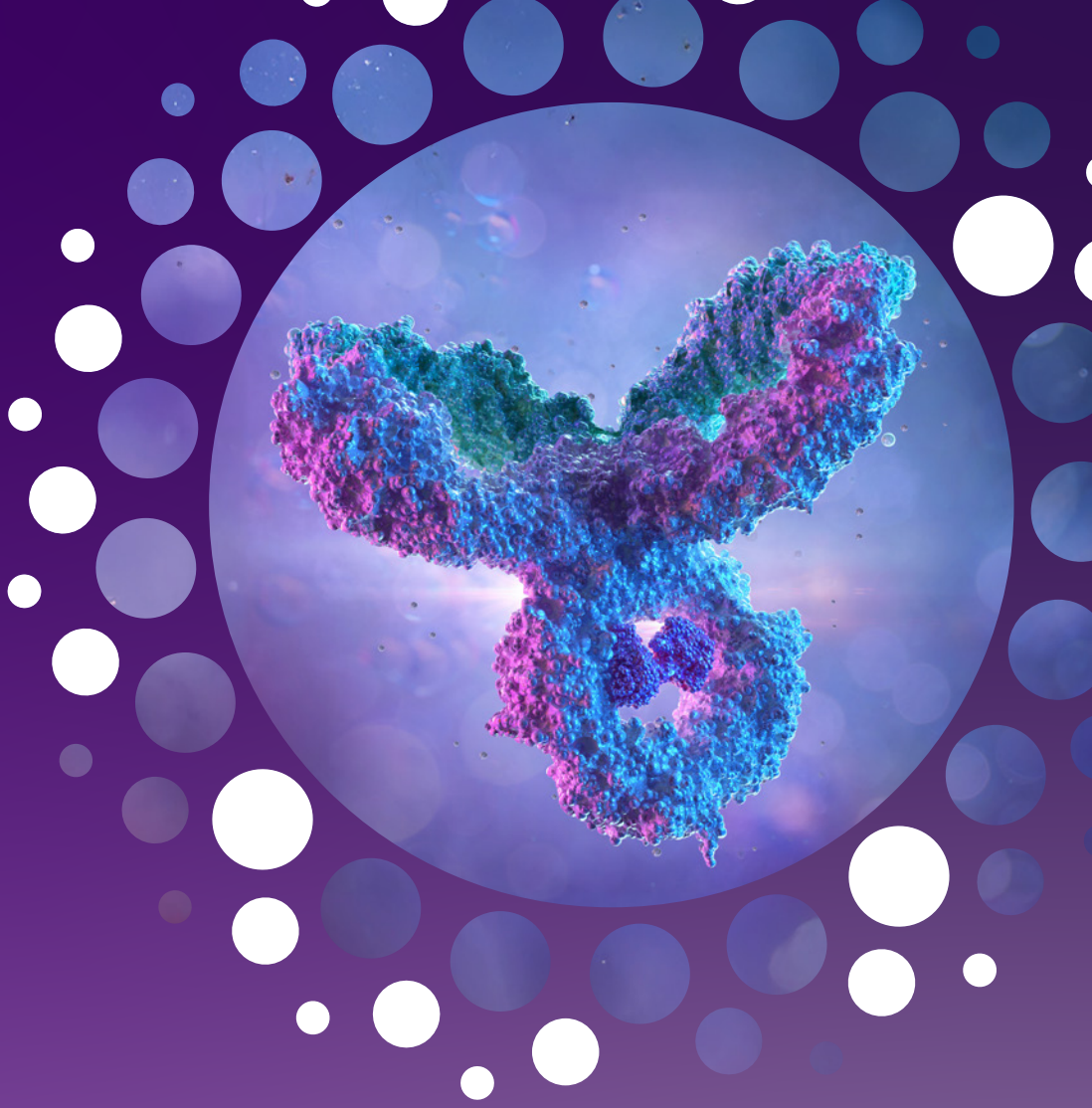

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