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The Next Wave Of Biosimilars: Why Hematology Is A High-Stakes Opportunity

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The Next Wave Of Biosimilars: Why Hematology Is A High-Stakes Opportunity

The biosimilars market is entering a new phase—one shaped not just by growth, but by urgency.

Multiple factors are reshaping the landscape, including a looming wave of biologics losing exclusivity, mounting pressure to control healthcare costs, and rapid advances in the science and technology required to replicate complex therapies. Together, these dynamics are accelerating both interest and investment in biosimilars across the world.

Nowhere is this more apparent than in hematology.

“The treatment of hematologic disorders relies heavily on high-cost biologics such as G-CSFs and thrombopoietin agonists. These products are major drivers of healthcare spending verses prescription volume,” says Kimberly Salgado, Head, Center for Biosimilar Drug Development at ICON. “That’s why they’re such high-value targets for biosimilar competition.”

But while the opportunity is there, the path to success is anything but easy. For developers, particularly those entering global markets for the first time, the next decade will demand not only speed but precision, foresight, and a fundamentally different approach to development, according to Salgado.

A Market Driven By Cost And Capability

Much of the momentum behind biosimilars comes from a simple reality: governments, payers, and health systems are under increasing pressure to reduce the cost of specialty drugs, particularly biologics, which can cost thousands of dollars per dose.

This financial pressure is especially pronounced in hematology, where biologics extend beyond G-CSFs to include erythropoiesis-stimulating agents (e.g., epoetin alfa, darbepoetin alfa), monoclonal antibodies used in hematologic malignancies (e.g., rituximab), and newer targeted therapies such as complement inhibitors (e.g., eculizumab). Many of these agents are high-cost and have been key targets for biosimilar competition.[1]

> “The reality is we’re going to break the bank if we don’t address this.”
>
> *Kimberly Salgado, Head, Center for Biosimilar Drug Development at ICON*

Biosimilars offer a pathway to competition—and ultimately, cost reduction. According to the US Food and Drug Administration (FDA), biosimilars have already generated billions in savings globally, with more expected as additional products enter the market.[2]

In hematology, this impact is already visible across multiple classes: biosimilars now exist for supportive care agents (epoetin alfa), as well as major therapeutic antibodies like rituximab, where adoption has increased steadily in real-world practice and created meaningful opportunities for cost savings and expanded access.[3]

At the same time, scientific advances are making biosimilar development more accessible than ever before. Improvements in analytical technologies, manufacturing processes, and global R&D capabilities—particularly across Asia-Pacific—have made it increasingly feasible to develop high-quality alternatives to complex biologics, according to Salgado.

Hematology has been a leading area for these advances, with early biosimilars developed for erythropoietin and G-CSFs, followed more recently by complex monoclonal antibodies such as rituximab and emerging agents like eculizumab—reflecting growing confidence in the ability to replicate even highly complex biologics.[4]

> Our capabilities for making these compounds have improved tremendously, even in the past five years.
>
> *Kimberly Salgado, Head, Center for Biosimilar Drug Development at ICON*

This combination of economic pressure and technical progress is setting the stage for the next major wave of biosimilars—one that will be heavily shaped by the upcoming patent cliff.

The Race Begins Before The Patent Expires

Over the next decade, a large number of biologics will lose patent protection, opening the door for biosimilar competition. According to data cited by the Biosimilars Council, 118 biologics are expected to face patent expiry between 2025 and 2034, representing a significant opportunity for future biosimilar development.[5]

In hematology, this pipeline is particularly significant because several widely used biologics—including monoclonal antibodies for hematologic malignancies and supportive care agents—have historically represented major revenue drivers, making them priority targets for biosimilar developers as patents expire.[6]

But the opportunity does not begin when patents expire—it begins years earlier.

"The timing is now," Salgado says. "Even with the changes in regulation, it takes time to develop these products. If you want to compete, you have to start early."

In biosimilars, being first to market can be a major differentiator. Early entrants often have the best chance of securing formulary placement, building provider trust, and setting the standard for future competitors. This first-mover advantage is especially relevant in hematology, where treatment pathways are highly protocol-driven and early adoption of a biosimilar can influence long-term prescribing patterns within institutions.[7]

"There's always a race," Salgado explains. "If another company demonstrates a higher level of similarity to the originator, it becomes very difficult for others to compete."

This reality is already influencing strategic decisions. Some developers, recognizing they are too far behind, are choosing to exit programs rather than continue investing in a losing race, according to Salgado.

High Value, High Complexity

While biosimilars span multiple therapeutic areas, hematology stands out for its commercial potential and its scientific complexity.

Many hematology biologics—such as those used to stimulate red or white blood cell production—are not only expensive, but also widely used in routine patient care. That combination creates a strong economic incentive for biosimilar development. They are also frequently integrated into standard-of-care regimens across oncology and chronic disease management, meaning even incremental cost reductions at scale can translate into substantial system-wide savings.[8]

At the same time, these therapies are among the most challenging to replicate.

> These are live-cell products, They're inherently more complex and even small differences can matter.
>
> *Kimberly Salgado, Head, Center for Biosimilar Drug Development at ICON*

Unlike small-molecule generics, which can be chemically identical to the originator compound, biosimilars must demonstrate a high degree of similarity across multiple dimensions.[9] This is especially important in hematology, where even small differences can affect outcomes such as immune response, transfusion needs, or tumor control.

Analytical Evidence Is Now The Cornerstone

One of the most significant shifts in biosimilar development is the increasing emphasis on analytical data.

Historically, large clinical trials played a central role in demonstrating biosimilarity. Today, regulators are placing far greater weight on detailed analytical characterization.

"The newest regulations are relying very heavily on the data you generate to show that your product is as similar as possible to the originator," Salgado says.

This includes everything from molecular structure and stability to functional activity and manufacturing consistency. Developers need to demonstrate similarity and also be able to explain and justify any differences. In hematology, this often requires precise functional assays tailored to the mechanism of action, such as measuring stimulation of erythropoiesis or antibody-mediated cytotoxicity.[10]

The challenge is that generating this data is highly complex and rarely follows a standard process.

"You have to fully characterize the molecule—how it works, how it's made, how stable it is," Salgado says. "That's not something you can just pull off the shelf."

Even the assays used to measure these properties often need to be developed from scratch and rigorously validated. In some cases, delays in assay development can hold up entire programs.

"Programs don't start on time because they can't get the assays to be repeatable," Salgado adds.

Where Developers Get It Wrong

Despite growing experience in the field, many developers continue to underestimate the importance of this analytical foundation.

> "The biggest mistake I see is over-reliance on the clinical trial."
>
> *Kimberly Salgado, Head, Center for Biosimilar Drug Development at ICON*

Some sponsors assume that a robust clinical study can compensate for gaps in analytical or manufacturing data. In practice, regulators increasingly prioritize strong analytical and functional evidence first, with clinical studies used more selectively to confirm biosimilarity or address any remaining uncertainty.[11]

"You can't just say, 'I'll prove it in the trial'" she explains. "You still have to demonstrate similarity at the analytical and manufacturing level."

Clinical trial design itself is another common pitfall. In some cases, developers attempt to study multiple indications simultaneously, introducing variability that can complicate the interpretation of results.

"The focus should be on demonstrating similarity in a sensitive, well-defined indication," Salgado explains. "Expanding the design to include too many variables can complicate the ability to draw clear conclusions."

In hematology, identifying this sensitive population is particularly important, as disease variability—such as differences across lymphoma subtypes or anemia etiologies—can impact trial sensitivity and outcomes.

There is also a tendency to underestimate timelines, particularly given the operational challenges of running biosimilar trials. Enrollment can be difficult, especially in markets where standard-of-care treatments are readily available and incentivized.

"These drugs are already on the market," she says. "So why would a patient or physician choose to participate in a trial?"

Manufacturing: The Hidden Risk

Strong analytical data is essential in biosimilar development, but manufacturing plays an equally important role.

Even minor variations in the production process can lead to differences in the final product—differences that may affect safety, efficacy, or regulatory approval.

> "Just because you can make it once doesn't mean you can make it the same way every time."
>
> *Kimberly Salgado, Head, Center for Biosimilar Drug Development at ICON*

Batch-to-batch variability remains a common challenge, particularly for complex biologics. Developers must demonstrate not only that their product matches the originator, but that it can be produced consistently at scale. This is particularly critical in hematology, where even modest changes in product activity could translate into measurable differences in laboratory parameters such as hemoglobin levels or neutrophil counts.[12]

Unexpected factors, though they may seem insignificant, can introduce variability.

"Even things like packaging can affect the product," she adds.

As delivery mechanisms evolve—for example, from vial-based administration to auto-injectors—additional

layers of complexity emerge, including device performance and combination product regulations.

Global Development Is No Longer Optional

At the same time, biosimilar development is becoming increasingly global.

Developers—particularly those based in Asia-Pacific—are expanding beyond their own markets and targeting the US and Europe. But doing so requires careful alignment with regulatory expectations, which continue to evolve.

“Every day there’s a new regulation or guidance,” Salgado says. “It can be very confusing, and even the feedback from agencies can vary.”

So, early and ongoing engagement with regulators is critical.

“If you know what product you’re targeting and have preliminary data, you should already be talking to the agencies,” she says.

This includes developing a clear global strategy—one that accounts for differences in regulatory requirements, clinical expectations, and market considerations across regions.

It also requires thinking beyond approval to long-term evidence generation. Real-world evidence, for example, is becoming an increasingly important component of biosimilar programs, yet is often underutilized, according to Salgado.

“Developers should be planning for how they’ll use real-world evidence from the beginning,” she notes.

In hematology, real-world data can play a key role in demonstrating long-term safety and effectiveness, particularly in chronic conditions where treatment duration extends beyond clinical trial timelines.[13]

Precision, Not Just Speed

As the biosimilars market continues to evolve, success will depend less on speed alone, and more on how strategically that speed is applied.

Developers must balance science, regulation, and global execution—often under significant time and cost pressure. Those that succeed will be the ones that invest early in the right capabilities, make informed strategic decisions, and adapt quickly to a changing landscape.

In this environment, experience matters.

From analytical strategy and regulatory engagement to clinical design and global operations, the ability to integrate expertise across disciplines can make the difference between a program that advances and one that stalls.

For Salgado, the stakes are not just scientific or commercial—they are personal.

“I’ve seen families destroyed by the cost of medical care,” she shares. “I want to get these treatments out there. I want to be the best at helping make that happen.”

That sense of urgency will shape what comes next, particularly in hematology, where the opportunity is significant, but the stakes are high.

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