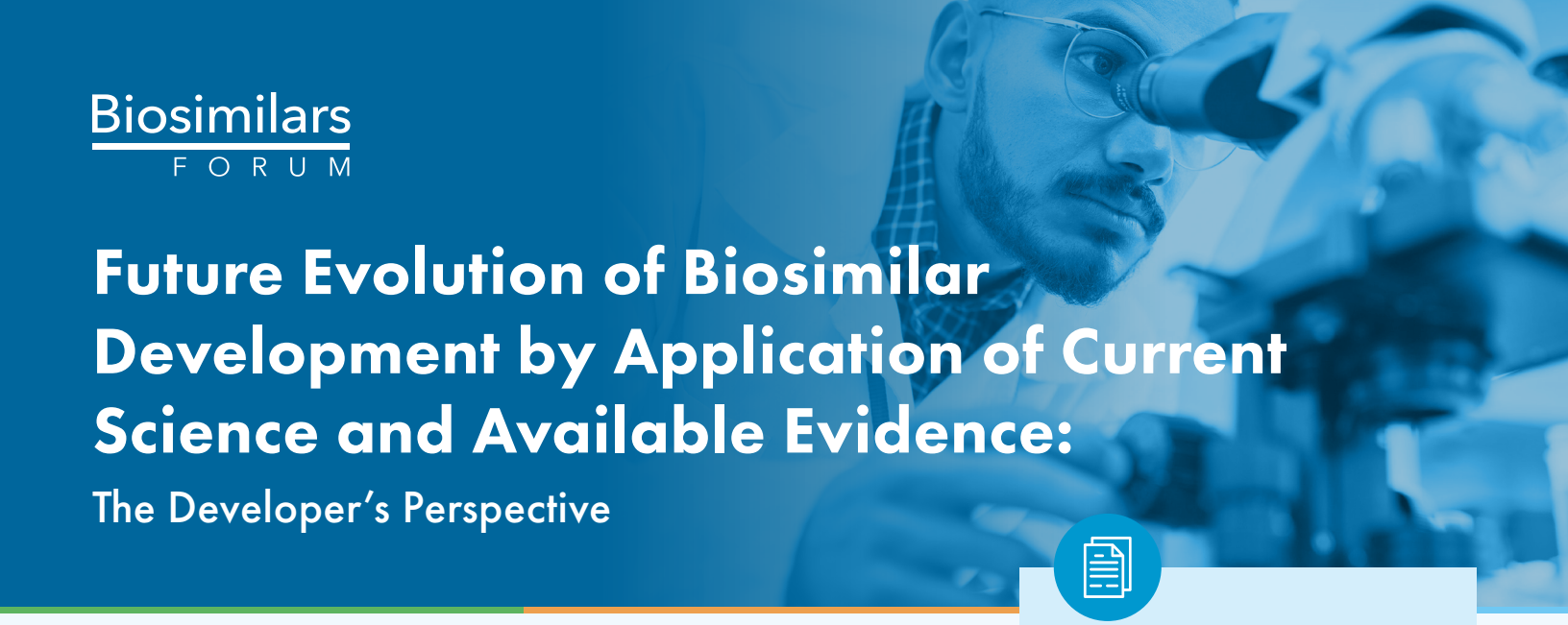
Biosimilars FORUM

Future Evolution of Biosimilar Development by Application of Current Science and Available Evidence:

The Developer's Perspective



Advancing the evolution of biosimilar development to reflect today's current science and available evidence will provide long-term sustainability to the biosimilar industry while enabling patients to access more and a wider variety of biological drugs without impacting safety or effectiveness.

Biosimilars have been available in the U.S. for over a decade and in Europe for almost two decades. When the regulatory pathway for biosimilars in the U.S. was created in the mid-2000s, the registration requirements reflected the science in routine use at that time. However, science and developers' experiences have progressed significantly. In fact, the biosimilars industry has advanced approval and launches of biosimilars in over 80 countries, achieving more than 2 billion patient days of global experience to date.

Further advancing biosimilar development will ensure consistency and high global standards for all biosimilars while maintaining the highest standards for patient safety. Now is the time to review the biosimilar development process to be more efficient and to incorporate current science and all available evidence.

The Biosimilar Forum's recommended action on biosimilar development is described in greater detail in the article Future Evolution of Biosimilar Development by Application of Current Science and Available Evidence: The Developer's Perspective. This manuscript was authored by Biosimilars Forum members Hillel P. Cohen, Matthew Turner, Dorothy McCabe, Gillian R. Woollett.

The article was published in BioDrugs, a peer-reviewed publication, on August 5, 2023.

What is a biosimilar?

A biosimilar is an FDA-approved biologic product that is approved based on the demonstration of a high degree of similarity to an FDA-approved reference biologic product. Biosimilars must also show no clinically meaningful difference to the reference product in terms of safety and effectiveness.

The availability of biosimilars has led to increased patient access and a lowering of healthcare costs. Even so, many patients who could benefit from biologics struggle to get timely and affordable access.

Now is the Time to Evolve Biosimilar Development

Now is the time to revise the current biosimilar development process to make future biosimilar development more efficient by applying current science and lessons learned.

The following opportunities to evolve development would expand worldwide access to biosimilars in a manner that does not compromise product quality, safety, and efficacy for patients.

Eliminate a routine requirement for a comparative clinical efficacy study

A very extensive analytical comparison of a proposed biosimilar and reference product exists using methods that are highly sensitive and accurate. Furthermore, a comparative pharmacokinetic study is conducted to show that the proposed biosimilar and reference product circulate within the body in a similar manner. Comparative efficacy studies are now

known to be less sensitive and discriminating than other methods and do not provide useful information. However, these studies are lengthy and expensive. By eliminating this routine requirement, it would enable biosimilar development for more and a wider variety of biological drugs, accelerate biosimilar development, and lower costs.

Utilize a risk-based approach for immunogenicity testing

Focusing on a risk-based approach for immunogenicity testing that would be applied as appropriate could further streamline development.

Modify US designation of interchangeability immediately and eliminate it in the future

The U.S. interchangeability designation was included in biosimilar legislation to address a hypothetical immunogenicity concern related to multiple switching events. In the 15+ years since the biosimilar pathway was established, the industry has learned that multiple switching events, whether between reference product and biosimilar or even between biosimilars, has no impact on patient safety, immunogenicity or effectiveness. Modification of the requirements recommended in the U.S. interchangeability guidance and possible elimination of this designation in the future would eliminate unnecessary clinical testing and remove a source of confusion for health care professionals and patients.

Eliminate the requirement for comparative PK testing of EU and U.S. reference products

These comparisons were conducted for the many biosimilars that are already approved in both the EU and the U.S. However, all data has revealed that these comparisons are not necessary. Removal of this requirement would simplify clinical study design and allow developers to focus on comparison the proposed biosimilar and reference product.

Develop science-based regulatory consistency, including quality and pharmacovigilance

This would ensure a high global standard for all biosimilars that are marketed everywhere in the world, ensuring that all patients can access safe and effective biosimilars.

Utilize real-world data and real-world evidence

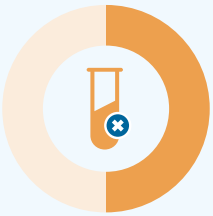
Leveraging data already acquired in many regions and patient populations would increase health care professional and patient trust in biosimilars.

Conclusion

Science and decades of experience demonstrate that there is a need to advance biosimilar development to reflect today's technologies and experiences. Robust biosimilar competition will be achieved through the evolution of biosimilar development, which will lead to increased competition and lower prices as more biosimilars are brought to the market.

It is projected that under the current biosimilar development paradigms, approximately 50% of biologic medicines on the market today will not have biosimilar competition due to the high cost and length of time for biosimilar development. Without future biosimilars, patients will not have access to these lower-cost medicines and the resulting cost savings.

The Biosimilar Forum's proposed evolutionary steps in biosimilar development will expand worldwide access to these increasingly essential treatments in a manner that does not compromise the quality, safety, and efficacy of biologics or biosimilars for patients.



It is projected that under the current biosimilar development paradigms approximately 50% of biologic medicines on the market today will not have biosimilar competition due to the high cost and length of time for biosimilar development.

The Biosimilars Forum

The Biosimilars Forum is a nonprofit organization working to advance biosimilars in the United States with the goals of expanding access and availability and improving healthcare outcomes. Since its inception, the Forum has worked to expand the uptake of biosimilars throughout the healthcare system through policies that will increase access for patients and lower costs through increased competition. Forum members represent companies with the most significant U.S. biosimilars development portfolios.