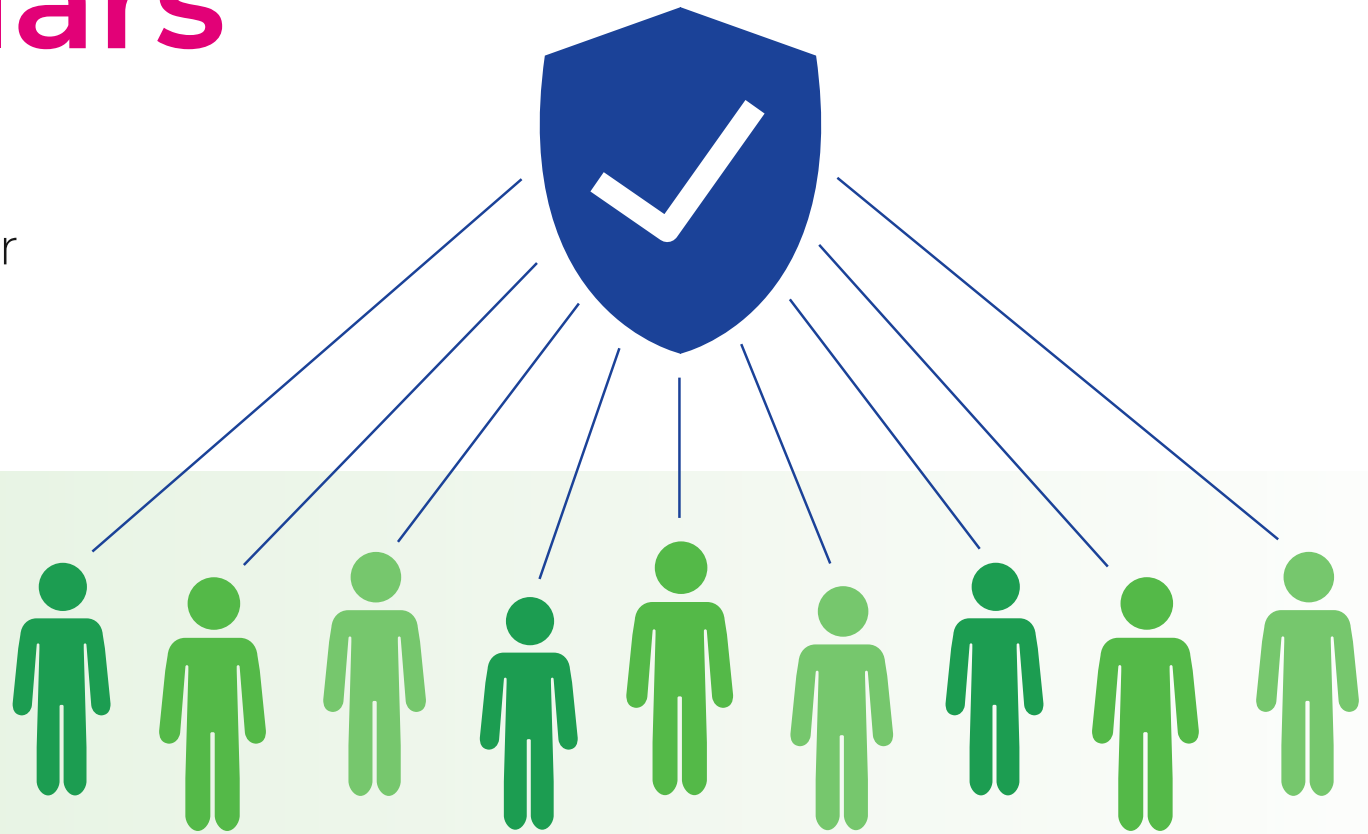
Building **Trust With Biosimilars**

Could biosimilars be a reliable option for your institution?



Biosimilars can be prescribed for patients with or without previous treatment history on an originator biologic.[1]
Learn how to make an impact by adopting with confidence.

How are biosimilars developed, and who are the appropriate patients?

Reference: 1. Prescribing biosimilar products. FDA website. Updated October 23, 2017. Accessed September 10, 2021. https://www.fda.gov/media/108103/download

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What are the goals of biosimilar development?

Biologics are highly complex molecules synthesized from a living source.[1] The complexity of these molecules requires a rigorous development and approval process for both originator biologics and biosimilars, with **unique goals for each approval pathway.**[2,3]

Goal of originator biologic development: Demonstrate the efficacy and safety of a proposed product.[3]

Goal of biosimilar development: Demonstrate no clinically meaningful differences in safety, purity, and potency from an approved reference biologic.[2,3]

- Preclinical research
- Clinical trial—Phase I
- Clinical trial—Phase II
- Clinical trial—Phase III

A biosimilar is proposed for an established originator biologic[2,3]

- Multifactorial analysis: structural and functional testing
- Comparative human PK/PD and immunogenicity studies
- Comparative clinical studies

The FDA established this process to create an abbreviated approval pathway for biosimilars.[4]

FDA, U.S. Food and Drug Administration; PD, pharmacodynamics; PK, pharmacokinetics.

Discover the building blocks of biosimilarity

References: 1. Biological product definitions. FDA website. Updated July 28, 2021. Accessed October 5, 2021. https://www.fda.gov/media/108557/download **2.** Scientific considerations in demonstrating biosimilarity to a reference product. Guidance for industry. FDA website. April 2015. Updated April 24, 2020. Accessed October 5, 2021. https://www.fda.gov/media/82647/download **3.** Christl L. FDA's overview of the regulatory guidance for the development and approval of biosimilar products in the US. FDA website. Accessed October 5, 2021. https://www.fda.gov/files/drugs/published/FDA%E2%80%99s-Overview-of-the-Regulatory-Guidance-for-the-Development-and-Approval-of-Biosimilar-Products-in-the-US.pdf **4.** Biosimilars Action Plan. Balancing innovation and competition. FDA website. July 2018. Accessed October 5, 2021. https://www.fda.gov/media/114574/download

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Biosimilar approval is supported by a rigorous demonstration of similarity

The development and approval process for biosimilars involves comprehensive comparative testing with an approved reference product. **Every step of the rigorous process helps provide evidence to support FDA approval.**[1]

What does biosimilarity mean?

NO CLINICALLY MEANINGFUL DIFFERENCES between the proposed biosimilar and the reference biologic in terms of safety, purity, and potency[1]

How is biosimilarity measured?[1]

- Molecular structure
- Mechanisms of action
- Pharmacokinetic interactions
- Distribution in the body
- Immune responses
- Overall efficacy and safety

This rigorous demonstration helps support the reliability of biosimilarity.[1,2]

FDA, U.S. Food and Drug Administration.

Learn more about the appropriate patients for biosimilars

References: 1. Scientific considerations in demonstrating biosimilarity to a reference product. Guidance for industry. FDA website. April 2015. Updated April 24, 2020. Accessed October 5, 2021. www.fda.gov/downloads/drugs/guidances/ucm291128.pdf **2.** Prescribing biosimilar products. FDA website. Updated October 23, 2017. Accessed September 10, 2021. https://www.fda.gov/media/108103/download

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Which patients are appropriate for a biosimilar?

The FDA approves a biosimilar for the same use as its reference biologic, often with the same indications and mechanisms of action. **The appropriate patients for biosimilars may be new patients as well as patients with a history on biologics.**[1]

When a biosimilar is used appropriately, patients and their prescribers may rely on there being[1]:

No clinically meaningful differences between the biosimilar and its reference biologic

For a practical example, in a review of 90 biosimilar transition studies[2,a]:

- **There were no clinically meaningful differences in efficacy** related to transitioning from an originator biologic to a biosimilar
- **The incidence of adverse events was similar** before and after transitions from an originator biologic to a biosimilar

[a]Studies for this review were gathered through a systematic search of medical literature databases and varied in size and methods used (as this review was designed to be inclusive, studies were not filtered by the rigor of their methodology). The studies included were not designed or powered to detect switch-related differences and could not be pooled in a meta-analysis for the end points of this review.

If a patient is considered appropriate for a biologic, they may be appropriate for a biosimilar.[1]

FDA, U.S. Food and Drug Administration.

How does the reliability of biosimilars benefit the health care system?

References: 1. Prescribing biosimilar products. FDA website. Updated October 23, 2017. Accessed September 10, 2021. https://www.fda.gov/media/108103/download **2.** Cohen HP, Blauvelt A, Rifkin RM, Danese S, Gokhale SB, Woollett G. Switching reference medicines to biosimilars: A systematic literature review of clinical outcomes. *Drugs*. 2018;78(4):463-478. doi:10.1007/s40265-018-0881-y

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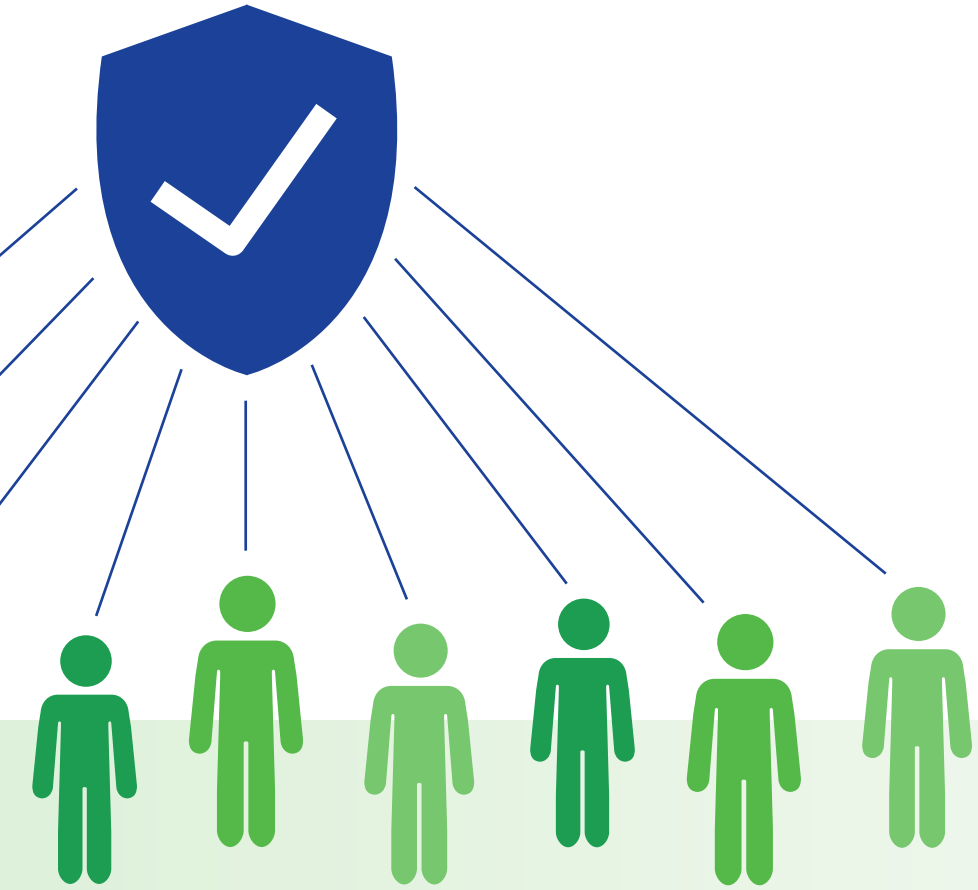
Make an **Impact** With Biosimilars



In summary:

How are biosimilars developed, and who are the appropriate patients?

1. An FDA-approved biosimilar will have been supported by a rigorous demonstration of similarity to an originator biologic.[1,2]
2. This process demonstrates no clinically meaningful differences between the proposed biosimilar and the reference biologic in terms of safety, purity, and potency.[1]
3. An appropriate patient for a reference biologic may also be appropriate for its biosimilar.[2]

How can your institution make an impact? As more practices and institutions adopt biosimilars with confidence, the potential for increased access and decreased costs to the health care system grows.[3]

Download this guide to adopting biosimilars in your institution

Download this guide to adopting biosimilars in your practice

FDA, U.S. Food and Drug Administration.

References: 1. Scientific considerations in demonstrating biosimilarity to a reference product. Guidance for industry. FDA website. April 2015. Updated April 24, 2020. Accessed October 5, 2021. www.fda.gov/downloads/drugs/guidances/ucm291128.pdf **2.** Prescribing biosimilar products. FDA website. Updated October 23, 2017. Accessed September 10, 2021. https://www.fda.gov/media/108103/download **3.** Mulcahy AW, Hlávka JP, Case SR. Biosimilar cost savings in the United States: initial experience and future potential. Published October 22, 2017. Accessed October 5, 2021. https://www.rand.org/content/dam/rand/pubs/perspectives/PE200/PE264/RAND_PE264.pdf

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