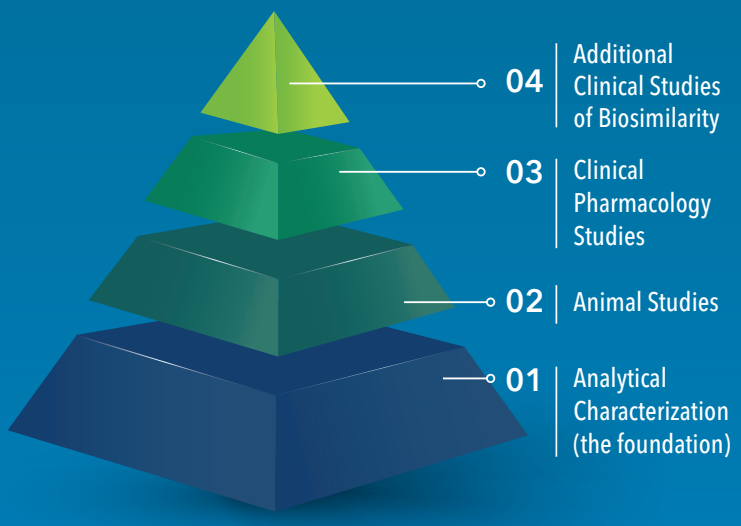
# FDA APPROVAL OF BIOSIMILARS

## WHAT IS THE APPROVAL PROCESS FOR BIOSIMILARS?

In 2009, the Biologics Price Competition & Innovation Act (BPCIA) created an abbreviated approval pathway for a class of biologics called biosimilars.[1] Even though the approval pathway is shorter, biosimilars must still undergo a rigorous evaluation by the Food and Drug Administration (FDA) in order to establish biosimilarity to the reference product and gain approval.[1]

In order to demonstrate biosimilarity to the reference product, a biosimilar manufacturer must provide the FDA with data showing that the biosimilar is highly similar to and has no clinically meaningful differences from the reference product in safety, purity, and potency. If the manufacturer demonstrates biosimilarity, the FDA may not require them to collect the same full data profile as the reference product, instead relying on the FDA's previous assessment of the safety and efficacy used to approve the reference product.[1]

### FDA PROCESS FOR EVALUATING BIOSIMILARS[1]




## WHAT TYPE OF DATA IS REQUIRED FOR APPROVAL OF A BIOSIMILAR?

Biosimilars are evaluated on a case-by-case basis and the exact data needs will be tailored to each application. The FDA may consider the following types of data when evaluating a biosimilar[1,2]:

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| Analytical Studies | To characterize the molecular profile of the biosimilar, demonstrating high similarity to the reference product, both structurally and functionally |
| Animal Studies | To assess toxicity of the biosimilar product |
| Clinical Pharmacology Studies | To provide evidence of safety, purity, and potency of the biosimilar. These studies may include pharmacokinetic and pharmacodynamic analyses |
| Additional Clinical Studies of Biosimilarity | **The goal of a biosimilar development program is to demonstrate high similarity between the proposed biosimilar product and the reference product,** not to independently establish the safety and efficacy of the proposed product |

## CAN A BIOSIMILAR BE APPROVED FOR AN INDICATION FOR WHICH THE REFERENCE PRODUCT IS APPROVED, WITHOUT BEING STUDIED IN THAT INDICATION?

Yes, a biosimilar can be approved for an indication, even if it was not specifically studied for use in that indication. This concept is known as **extrapolation**. If the body of evidence supporting the biosimilar demonstrates biosimilarity in at least one of the reference product's indications, expanded approval for the reference product's other indications may be granted by the FDA. The FDA draws on available data, information, and scientific justification provided in the biosimilar application, in addition to the FDA's previous findings on the safety and efficacy of the reference product, to make a final determination on whether or not to extrapolate.[2]

**Want more information about biosimilars?**
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**References: 1.** US Food and Drug Administration. Labeling for biosimilar products. *Guidance for Industry*. July 2018. https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm493439.pdf. Accessed July 20, 2018. **2.** US Food and Drug Administration. Scientific considerations in demonstrating biosimilarity to a reference product. *Guidance for Industry*. April 2015. https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm291128.pdf. Accessed June 25, 2018.

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